DIGITAL HEALTH PRODUCT CATEGORIES

After reading this factsheet you should:

- Understand digital health product categories.
- Have a basic knowledge of the systems used to categorize digital health products.

Digital Health Product Categories

The term "digital health" refers to a broad range of goods and services that make use of technology to enhance patient care, healthcare delivery, and wellness management. The following are some of the most well-known types of digital health product categories:

- Telemedicine and Telehealth: Platforms and applications that allow for remote consultations and healthcare services including virtual visits and remote monitoring.
- Mobile Health (mHealth) Apps: Apps for managing personal health such as tracking medications, nutrition, and stress.
- Electronic Health Records (EHRs) and Health Information Systems: Systems for managing, exchanging, and storing patient health information.
- Wearable Devices: Wearable devices that collect data about your health e.g., smartwatches, continuous glucose monitoring technology.
- Remote Patient Monitoring: Technologies that enable medical professionals to remotely monitor aspects of a patient's health e.g., vital signs, weight, blood pressure and heart rate.
- Digital Therapeutics: Software-based interventions created to prevent, control, or treat a particular condition e.g., web-based apps, smartphone apps, virtual reality software.
- Health Information Exchange (HIE): Platforms and systems that permit healthcare professionals to securely share and exchange patient health information.
- Health Analytics and Big Data: Large-scale platforms that gather, examine, and draw conclusions from health-related data e.g., clinical decision-making processes guided by data.
- Artificial Intelligence and Machine Learning (AI/ML): Technologies that handle and analyse healthcare data using algorithms and computational models e.g., systems for triage and diagnosis powered by AI, ML techniques for early disease detection and risk assessment.
- Personalized Medicine and Genomics: Products and services that use genomic data and data from personal healthcare records to customise therapy e.g., platforms for the analysis of genomic data.

What systems are used to categorise digital health products?

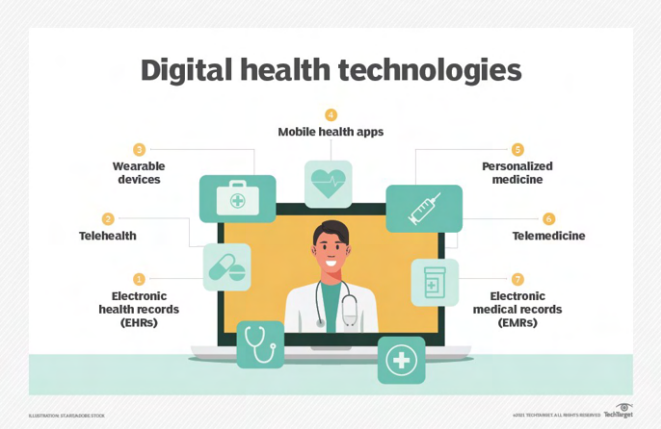
Digital Health products do not have one standard classification system. The following are some of the most frequently used classification systems:

World Health Organisation- ICHI

The International Classification of Health Interventions (ICHI) is not only concerned with digital health products, however it offers a framework for classifying health interventions, which includes those that are supplied electronically. Each intervention is identified by a title with a unique seven-character code, or "stem code," covering three axes:

- Target: Describes the health issue, demographic, or situation where the intervention is to be used e.g., ICHI Code: TB001 - "Health behaviour: Healthy individuals"
- Action: Details the precise action or procedure carried out as part of the intervention e.g., ICHI Code: TA007 - "Therapeutic: Health promotion"
- Means: Describes the tools, equipment, or procedures used to execute the intervention e.g., ICHI Code: MD000 - "No qualifier"

By combining codes from these three axes (ICHI Code: TB001-TA007-MD000), the digital health item is a mHealth app (Means) created to promote health (Action) and target healthy people (Target) to assist in keeping track of and enhancing general health and wellness.



World Health Organisation- DHIs

The WHO Classification of Digital Health Interventions (DHIs) categorises the various ways that mobile and digital technology are employed to serve health system demands. It separates digital health interventions into 4 categories: Interventions for clients, Interventions fort healthcare providers, Intervention for health system or resource managers, Interventions for data services. This classification system should be used in tandem with the list of Health System Challenges to describe how technology is being used to meet specific health demands.

European Union- MDR/IVDR

The EU has no categorization system solely focused on digital health products. The classification may change depending on the product's intended use, level of risk, and technological features. Medical Devices Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR) apply to digital health goods that meet the definition of medical devices. The following are typical categories of digital health products covered by medical device regulations:

- Software as a Medical Device (SaMD)
- Mobile Medical Applications
- In Vitro Diagnostic Devices
- Wearable Health Device

US- FDA

The Food and Drug Administration (FDA) has provided some guidance on the categorisation of digital health products. Certain digital health products are subject to FDA regulatory oversight, particularly those that fall under the definition of medical devices. The following are some digital health subgroups that the FDA has defined:

- Software as a Medical Device (SaMD)
- Artificial Intelligence and Machine Learning (AI/MK) in Software as a Medical Device (SaMD)
- Device Software Functions Including Mobile Medical Applications
- Medical Device Data Systems (MDDS)
- Medical Device Interoperability
- Cybersecurity
- Telemedicine
- Wireless Medical Devices