

DIGITAL HEALTH INDUSTRY CATEGORIZATION

Digital health products have many different purposes and functions. End users, clinicians, and payers should understand these differences and know what to expect from each product in terms of function, clinical evidence, and regulatory oversight.

This categorization is based on products' primary mechanism of action at the functional level and will be updated regularly to reflect the quickly evolving digital health industry.

DIGITAL HEALTH

DIGITAL MEDICINE

DIGITAL THERAPEUTICS

DEFINITION	Digital health includes technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.	Digital medicine includes evidence-based software and/or hardware products that measure and/or intervene in the service of human health. ¹	Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease. ²
CLINICAL EVIDENCE	Typically do not require clinical evidence.	Clinical evidence is required for all digital medicine products.	Clinical evidence and real world outcomes are required for all DTx products.
REGULATORY OVERSIGHT	These products do not meet the regulatory definition of a medical device ³ and do not require regulatory oversight.	Requirements for regulatory oversight vary. Digital medicine products that are classified as medical devices require clearance or approval. Digital medicine products used as a tool to develop other drugs, devices, or medical products require regulatory acceptance by the appropriate review division.	DTx products must be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.
PRODUCT EXAMPLES	Data & information capture, storage, and display <ul style="list-style-type: none"> • User-facing technologies <ul style="list-style-type: none"> - Lifestyle apps - Fitness trackers - Nutrition apps - Medication reminder apps - Scheduling apps • Health Information Technology (HIT)⁴ <ul style="list-style-type: none"> - Electronic medical record systems - Electronic prescribing⁵ and order entry systems • Consumer health information <ul style="list-style-type: none"> - Online repositories - Personal health records - Patient portals 	Measurement products <ul style="list-style-type: none"> • Digital diagnostics <ul style="list-style-type: none"> - Software-driven connected technologies that detect or confirm the presence of a disease or condition of interest or to identify individuals with a subtype of the disease • Digital biomarkers <ul style="list-style-type: none"> - Digital tools that measure patient characteristics that are objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention - Includes all BEST biomarkers • Electronic clinical outcome assessments <ul style="list-style-type: none"> - Digital measures of how patients feel, function, or survive 	Software that delivers a therapeutic intervention <p><i>Medical claims include:</i></p> <ul style="list-style-type: none"> • Treat a disease Digital therapeutics that deliver a medical intervention to treat a disease. • Manage a disease Digital therapeutics that deliver a medical intervention to manage a disease. • Improve a health function Digital therapeutics that deliver a medical intervention to improve a health function and/or prevent a disease.

PRODUCT EXAMPLES
(continued)

Data & information transmission

- **Telehealth**
 - Telemedicine virtual visits
 - Remote care programs that do not include remote monitoring
- **Decision support software that:**⁶
 - Presents information for independent clinician review
 - Does not make recommendations that the user could not find through channels other than the software
- **Enterprise support**
 - Clinical trial operations & management tools
 - Trial management software
 - Trial recruitment platforms
- **Clinical care administration & management tools**
 - Revenue cycle management tools
 - Clinical staffing management tools
 - Length of stay monitoring and management tools

Measurement products *(continued)*

- **Remote patient monitoring**
 - Remote monitoring tools
 - Medication adherence tools
 - Sensor technologies that measure vitals and physiologic data
- **Decision support software that:**⁷
 - Relies on data inputs from medical imaging or in vitro diagnostic devices
 - Process or analyze this information without clinician input

Measurement & intervention products

- **Digital companion**⁸
 - Digital component integrated with either a drug or biologic
 - Ingestible sensors
 - Connected drug delivery device
 - Insulin pump
- **Digital products that both 1) measure *and* intervene, and 2) do not require human intervention to serve primary purpose**
 - Artificial pancreas
 - Pacemaker
 - Cochlear implant
 - CPAP

*Core principles all digital therapeutics must adhere to:*⁹

- Prevent, manage, or treat a disease
- Deliver a software-driven medical intervention
- Employ design, manufacture, and quality best practices
- Ensure end user engagement
- Implement privacy and security protections
- Apply product deployment and maintenance best practices
- Conduct clinical trials and publish results
- Undergo applicable regulatory reviews
- Make appropriate claims
- Utilize real world outcomes

1 <https://www.dimesociety.org/index.php/defining-digital-medicine>

2 <https://www.dtxalliance.org/dtxproducts/>

3 It is important to check with local regulatory requirements in each jurisdiction the product is manufactured, registered, or used in.

4 In the United States, ONC-certified EHR functions are not devices according to the FD&C Act, as amended by 21st Century Cures Act.

5 In the United States, while these do not require FDA oversight, there may be rules within specific states that govern these technologies.

6 <https://www.fda.gov/media/109618/download>

7 Ibid.

8 Note: 1) integration of the digital tool with an existing drug or biologic requires a label change for the drug or biologic, and 2) regulatory requirements may recognize digital tools coupled with a drug or biologic as a combination product.

9 <https://www.dtxalliance.org/aboutdtx/>