

DTx Product Categories*

DIGITAL HEALTH			
DIGITAL MEDICINE			
DIGITAL THERAPEUTICS			
Digital therapeutics (DTx) that meet Industry Core Principles are generally classified into one of three categories based on the product's primary purpose.			
	TREAT A DISEASE	MANAGE A DISEASE	IMPROVE A HEALTH FUNCTION**
Clinical endpoints	Must deliver a therapeutic intervention and use clinical endpoints to support product claims	Must deliver a therapeutic intervention and use clinical endpoints to support product claims	Must deliver a therapeutic intervention and use clinical endpoints to support product claims
Clinical evidence	Clinical trials and ongoing evidence generation required	Clinical trials and ongoing evidence generation required	Clinical trials and ongoing evidence generation required
Level of medical claims	Medium to high risk claims	Medium to high risk claims	Low to medium risk claims
Regulatory oversight	Third-party validation of efficacy and safety claims by regulatory or equivalent national body	Third-party validation of efficacy and safety claims by regulatory or equivalent national body	Degree of oversight depends on local regulatory frameworks
Patient access	Prescription required	Over-the-Counter OR Prescription required	Direct-to-Consumer, Over-the-Counter OR Prescription required

*Update to the [Industry Report](#), *Digital Therapeutics: Combining Technology and Evidence-based Medicine to Transform Personalized Patient Care* (p. 10).

**Includes digital therapeutics that prevent a disease.