

Digital Therapeutics Industry DTx Core Principles

All products that meet the definition of a digital therapeutic (DTx) should adhere to these foundational principles:

- 1 Incorporate design, manufacture, and quality best practices
- 2 Engage end users in product development and usability processes
- 3 Incorporate patient privacy and security protections
- 4 Apply product deployment, management, and maintenance best practices
- 5 Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals
- 6 Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
- 7 Make claims appropriate to clinical evaluation and regulatory status
- 8 Collect, analyze, and apply real world evidence and/or product performance data