

Digital Therapeutics (DTx)



Software as Medicine

- Evidence-based interventions
- Behavior modification programs
- Cognitive behavioral therapy
- Disease management apps

Regulatory Pathways

- FDA approval process
- CE marking in Europe
- Clinical trial requirements
- Post-market surveillance

Clinical Evidence

- Randomized controlled trials
- Real-world evidence

Reimbursement Models

- Insurance coverage expanding
- Value-based pricing

- Patient-reported outcomes
- Outcome-based payment
- Direct-to-consumer options

Market Growth: Expected to reach \$13B by 2028, driven by chronic disease management and mental health