

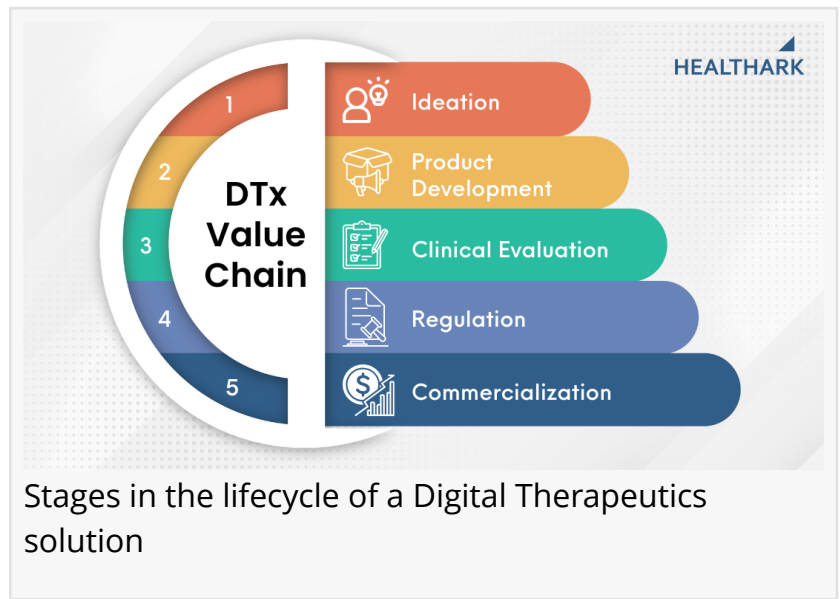
# Playbook for Digital Therapeutics (DTx): From Ideation to Commercialization

*Digital therapeutics (DTx) deliver evidence-based interventions driven by software programs to prevent, manage, or treat a disease, or improve a health function*

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Advancements in digital health and its widespread adoption are boosting the development and commercialization of digital health solutions. Within the Digital Health umbrella, digital therapeutics (DTx) deliver evidence-

based therapeutic interventions that are driven by software programs to prevent, manage, or treat a medical disorder or disease, or improve a health function.



Stages in the lifecycle of a Digital Therapeutics solution

The global digital therapeutics market is expected to hit \$13.8 billion by 2027, growing at a 21% rate annually from 2019. DTx funding has also observed a boost - grown at a CAGR of 69% from 2018 to 2021 and has reached \$3.4 billion. India's DTx market, despite its nascency, is set to thrive due to the fast paced tech adoption in healthcare, rising prevalence of chronic diseases and improved awareness of preventive healthcare reflected in the substantial boost in the venture capital investments.

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*Dr. Purav Gandhi*

[Healthark Insights](#) and [CIIE.CO](#) have been extensively studying the DTx phenomenon and have jointly launched a

[Digital Therapeutics \(DTx\) Playbook](#) for innovators aspiring to work in this space. The playbook claims to be a one-stop knowledge repository and a starter kit for all stakeholders willing to explore this space.

The playbook describes the entire lifecycle of a Digital Therapeutics solution, whether

prescriptive or non-prescriptive. Companies generally start with identifying the unmet patient needs and pain points in specific disease journeys during 'Ideation'. This is followed by 'Product Development' where software is built to solve the problem through robust clinical protocols, while complying with data security protocols and other standards & guidelines. 'Clinical evaluation' is conducted to demonstrate product safety and efficacy.

'Regulation' phase focuses on review and approval through credible authorities like FDA (US), CE (EU) or any other regulatory agencies. Approval of 80+ DTx solutions testifies that there's a friendly regulatory environment. The playbook describes regulatory requirements based on the nature of the DTx solution.

Once approved, the products also have to undergo the challenge of 'Commercialization', which includes both ensuring access and reimbursement. The playbook describes collaborative distribution models to drive access, and examples of real-world evidence based models to demonstrate outcomes for improved reimbursement. Complementing the traditional methods, digital therapeutics will continue to redefine medical practice, patient management and commercialization of treatments.

## About Healthark Insights

Healthark insights is a global management consulting firm developed by a team of experts from diverse fields such as consulting, pharma, medicine, medical devices, digital health, public health, and management with a common vision to cater to the healthcare and life sciences industry, along with a relentless focus on delivering executable solutions.

Healthark Insights team helps customers make critical decisions every day through expertise that combines deep domain knowledge, rigorous research, and analysis, understanding of markets, technology, and experience. With the right experience and expertise, the team not only provides insights but also works closely with clients to execute the strategy that they have helped develop.

## About CIIE.CO

CIIE.CO is the Innovation Continuum spreading from incubation, acceleration, seed, and growth funding to research. Founded at IIM Ahmedabad in 2002, CIIE.CO has grown to fill the multiple, ever-evolving gaps in the innovation-driven entrepreneurship ecosystem in India. Among various initiatives, CIIE.CO has conceptualized and hosted India's first accelerator - iAccelerator, created India's first cleantech-focused fund called INFUSE Ventures, designed and hosted one of India's largest accelerator programs - The Power of Ideas. Overall, CIIE.CO has accelerated over 1000+ entrepreneurs, invested in over 200+ startups, mentored and coached over 5000 startups and inspired over 700000 with its publication - Stay Hungry Stay Foolish.

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