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Reprogramming Chronic Care: AI-Driven Digital Therapeutics for a Connected, Personalized and Equitable Health Future

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ABSTRACT

Background: Non-communicable diseases such as diabetes, cardiovascular disease, and mental disorders contribute to 74% of global annual deaths, creating a major strain on healthcare systems. Conventional episodic care models are inadequate for continuous management, highlighting the need for innovative solutions.

Purpose: This review systematically evaluates the role of AI-powered Digital Therapeutics (DTx) in chronic disease management, examining clinical evidence, therapeutic outcomes, regulatory frameworks, and future integration with multidisciplinary healthcare systems, with a focus on low- and middle-income settings such as India.

Methods: A comprehensive literature search of clinical trials, meta-analyses, and real-world studies was conducted. Regulatory frameworks like the FDA's Software as a Medical Device (SaMD) and India's Ayushman Bharat Digital Mission (ABDM) were analyzed to assess the positioning of Digital Therapeutics (DTx) in healthcare systems.

Results: Digital therapeutics (DTx) showed significant advantages in chronic disease management: HbA1c reduction of 0.67% in Type 2 Diabetes patients, improved hypertension control with 84% of patients maintaining sustained blood pressure control over three years, and PHQ-9 score reductions by 7.3 points in depression. The AI-driven DTx platform provided real-time adaptive interventions using digital biomarkers and phenotyping. Despite these outcomes, widespread adoption faces challenges from low digital literacy, regulatory uncertainty, and inadequate reimbursement structures, especially in India.

Conclusion: AI-powered Digital Therapeutics (DTx) offer transformative solutions for chronic disease management by enabling personalized, adaptive care. Integrating DTx with Electronic Health Records (EHRs) enhances clinical decision-making and preventive care, but implementation is hampered by regulatory fragmentation and technological gaps.

1. Introduction

Chronic diseases, including cardiovascular conditions, cancer, respiratory disorders, and diabetes, are the leading causes of global morbidity and mortality, accounting for 74% of annual deaths worldwide (Folkmann *et al.*, 2024; Hacker, 2024). These non-communicable diseases (NCDs) are often influenced by lifestyle factors like physical inactivity, poor nutrition, and tobacco use, as well as socio-environmental conditions like poverty and stressful living circumstances (Shantz & Elliott, 2020). The global burden of chronic conditions is straining healthcare systems and necessitating innovative approaches to disease management (Carmina *et al.*, 2023).

Traditional episodic care models are inadequate for sustained behavioral change and long-term patient engagement, prompting a shift towards technology-driven strategies (Mann & Lawrence, 2022). Emerging at the intersection of software, clinical validation, and regulatory control, Digital Therapeutics (DTx) are evidence-based therapies that have been shown to deliver improved patient outcomes. As per the Digital Therapeutics Alliance: "Digital Therapeutics (DTx) deliver evidence-based therapeutic interventions to patients that are driven by software to prevent, manage, or treat a broad spectrum of physical, mental, and behavioral conditions" (Dang *et al.*, 2020).

Digital Therapeutics (DTx) are subjected to randomized controlled trials, receive regulatory approval, and, in

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the same way as pharmacotherapies, deliver prescribable interventions. Unlike typical mHealth apps centered on reminders, wellness content, and health tracking, DTx has to prove clinical efficacy, meet regulatory demands, and often get formal reimbursement (Fürstenau *et al.*, 2023). Table 1 offers a clear comparison of core differentiators between Digital Therapeutics (DTx), general mHealth applications, and telehealth services, summarizing key factors such as therapeutic claims, regulatory approvals, and use cases in clinical practice (Ali *et al.*, 2024; Singh & Landman, 2017).

Digital Therapeutics (DTx) growth is driven by innovations in wearables, mobile platforms, real-world evidence, and artificial intelligence/machine learning (AI/ML) platforms that allow for real-time data capture and adaptive therapeutic delivery. A review from 2021 demonstrated modern Digital Therapeutics (DTx) source power from four tools of technology (data preprocessing, algorithmic procedures, Human-Computer Interaction (HCL), and treatment recommendation system), highlighting their strong computational support. These systems manage and synchronize behavioral logs, biometric streams, and environmental data to deliver personalized, context-aware interventions in areas like management of diabetes, mental health, respiratory care, and cardiovascular rehabilitation, along with other chronic conditions (Hu *et al.*, 2023; Vasdev *et al.*, 2024). Digital Therapeutics (DTx) have shown significant clinical efficacy across various chronic diseases.

A meta-analysis of Digital Therapeutics (DTx) studies from 2017-2022 reported a substantial weighted average effect size of 1.13 (95% CI: 0.91-1.36), which indicates a moderate to large therapeutic impact (Seo *et al.*, 2024). Digital Therapeutics (DTx) have shown promise in improving outcomes for conditions like Alzheimer's disease, rheumatoid arthritis, and depression (Biskupiak *et al.*, 2024).

In real-world data, interventions like the Hello Heart digital hypertension program achieved sustained control in 84% of stage 2 HTN patients over 3 years (Dang *et al.*, 2020). While digital CBT platforms like Meru Health showed PHQ-9 reduction of 7.3 points with effect sizes up to 1.7. Despite robust growth and new regulatory imperatives like the Food and Drug Administration (FDA)'s existing device pathways in the U.S. and the DiGA fast-track in Europe, Digital Therapeutics (DTx) continues to encounter systemic barriers. These encompass segmented international regulation, low knowledge among both clinicians and patients, and infrastructure deficiencies, especially in emerging markets such as India, which is effective in the digital ecosystem with Ayushman Bharat Digital Mission (ABDM) but lacks Digital Therapeutics (DTx) guidelines that are detailed (Wang *et al.*, *2023*).

Personalized medicine in India faces significant challenges despite its potential to revolutionize healthcare (Kaushik & Gupta, 2025). Limited genetic data infrastructure, human prescribing variability, and regional disparities in specialist care access hinder its implementation (Naithani *et al.*, 2021). Inadequate patient stratification, real-time monitoring limitations, and treatment non-adherence due to behavioral and literacy barriers further complicate personalized prescribing (S & R, 2024). The integration of multi-omics data offers a promising solution but introduces complexities in data integration and analysis (Molla & Bitew, 2024). Ethical considerations, including equitable access and privacy, remain critical for responsible implementation (S & R, 2024). Despite these challenges, personalized medicine shows potential in combating antibiotic resistance that reduces treatment costs for complex diseases like cancer and improving outcomes in conditions like lung cancer and rheumatoid arthritis (Kaushik & Gupta, 2025). Digital Therapeutics (DTx) are emerging as transformative tools in healthcare, leveraging artificial intelligence (AI) to provide personalized interventions and improve patient outcomes.

Artificial intelligence (AI)-driven Digital Therapeutics (DTx) platforms utilize machine learning, natural language processing, and computer vision to process real-time patient data, predict health trajectories, and deliver tailored treatments (Mirza *et al.*, 2025). Recent studies demonstrated the effectiveness of Digital Therapeutics (DTx) in managing chronic conditions like T2DM and HTN. A Digital Therapeutics (DTx) platform using continuous glucose monitoring and an artificial intelligence (AI) algorithm showed significant improvements in HbA1c level and weight reduction for diabetes patients (Kannenberg *et al.*, 2024a). This comprehensive review aims to define and conceptualize digital therapeutics (DTx) that explore mechanisms of action, analyze clinical evidence across therapeutic areas, and chart future directions in a multidisciplinary healthcare framework, especially their integration in personalized medicine to overcome current human and synthetic limitations.

2. Defining Digital Therapeutics (DTx)

Digital Therapeutics (DTx) is now a different, clinically proven class of digital health that has been introduced through the correlation of software, patient care, and regulatory requirements. Digital Therapeutics (DTx) is "evidence-based therapeutic treatment created to augment or replace current medical treatment and is powered by superior software programs to prevent, treat, or manage a wide spectrum of medical conditions and diseases," as defined by the Digital Therapeutics Alliance. Unlike other mHealth or wellness apps that provide reminders and data tracking, Digital

Therapeutics (DTx) actively induce therapeutic responses based on clinical trial evidence consistent with treatment, do so much like a pharmacotherapy, and are frequently prescribed by prescribers (Crisafulli *et al.*, 2022a; Yoo *et al.*, 2023). It is important to distinguish between them, however, because Digital Therapeutics (DTx) must satisfy regulatory requirements, clinical efficacy endpoints, and "integration" if they are expected to provide value to the system (Kukreja *et al.*, 2023). At its most general, digital health is telemedicine, EHRs, wearables, and health education platforms. In that world, mHealth would pertain to apps and wearables akin to fitness and monitoring products but which generally fall short of therapeutic validation or prescription details (Perakslis & Ginsburg, 2021). Telemedicine delivers remote clinical services that focus on access and convenience but not important therapeutic software. Digital medicine includes medical-grade devices (e.g., CGMs and smart insulin pens) that are regulated by the FDA, clinically substantiated software-as-therapy, but not standalone software therapy. In contrast, Digital Therapeutics (DTx) are 'prescribable,' software-only, evidence-based interventions, with their outcomes established through rigorous clinical trials and frequently reimbursed (Zovi *et al.*, 2025). There are some variations in regulations; however, when it comes to Digital Therapeutics (DTx), they tend to be classified as Software as a Medical Device (SaMD). In the US, the Food and Drug Administration (FDA) approaches Digital Therapeutics (DTx) through pre-existing medical device pathways and requires demonstration of safety and efficacy for medical claims (Wang *et al.*, *2023*). The US Food and Drug Administration (FDA) Digital Health Center of Excellence has outlined pathways for regulation of prescribing and non-prescription Digital Therapeutics (DTx) and adjusted for submission processes to be aligned with Software as a Medical Device (SaMD) regulation (Anthony Watson *et al.*, 2023). In the European Union, Digital Therapeutics (DTx) are regulated under the EU Medical Device Regulations (MDR, EU 2017/745), requiring CE marking and a quality management system like ISO 13485 (Sharma & Luthra, 2023). Emergence of Digital Therapeutics (DTx) and its technological classification Digital Therapeutics (DTx) could be technologically categorized into four main groups. Stratified Use of App-Based Intervention to Deliver Digital Intervention (e.g., BlueStar for diabetes) offering structured coaching using algorithms and messaging to encourage adherence and behavior change. Artificial intelligence/ machine learning (AI/ML)-enabled systems analyze data about patients from wearables to self-reported measures that help to personalize interventions in mental health, cardiometabolic conditions, and beyond (Zovi *et al.*, 2025). Sensor/wearable-driven platforms are based on real-time physiologic monitoring with algorithmic feedback, including apps like CODA that are linked to CGMs or smart inhalers. Moreover, therapeutics leverage VR/XR to provide immersive contexts for the management of pain, trauma treatment, or rehabilitation of cognitive skills, and some of these have been described in the latest regulatory approvals garnered at short notice (Zheng *et al.*, 2024). Between 2023 and 2024, Digital Therapeutics (DTx) worldwide markets resulted in the widespread adoption of metabolic, mental health, cardiovascular, pulmonary, and neurological apps. About 30% were metabolic, including obesity and diabetes, followed by mental health apps (25%), cardiovascular (20%), pulmonary (10%), neurological (10%) like Attention-Deficit/Hyperactivity Disorder (ADHD) and dementia, and other uses such as sleep and substance use (approximately 5%). This distribution reflects the relative maturity and adoption of Digital Therapeutics (DTx) across various chronic disease domains, highlighting metabolic disorders as early adopters due to higher patient engagements and measurable biomarker outcomes. "Figure 1" and "Table 1" (Refolo *et al.*, 2022). Personalization in Digital Therapeutics (DTx) significantly increases treatment adherence in chronic care by integrating patient-specific data to deliver tailored interventions (Vikram, 2023). Recent studies showed the effectiveness of machine learning (ML)-based digital therapeutics (DTx) platforms for Type 2 Diabetes Mellitus (T2DM) management. A study showed that an AI-driven digital therapeutics (DTx) platform achieved a 0.67% HbA1c reduction in the complete cohort and a 1.08% reduction in poorly controlled patients over three months compared to standard care ($p<0.001$) (Kannenberg *et al.*, 2024). One study demonstrated that an AI-based integrated digital healthcare platform resulted in significantly greater HbA1c reductions as compared to routine care, with decreases of -0.32% at 24 weeks and -0.28% at 48 weeks in the digital platform group compared to minimal changes in controls (Bin Lee *et al.*, 2023). Digital therapeutic (DTx) systems demonstrate particular promise in chronic disease management, where AI algorithms analyze physiological data streams to generate predictive forecasts and facilitate timely clinical interventions, ultimately reducing hospitalizations and empowering patient self-management. Such intelligent systems enhance therapeutic efficacy by monitoring adherence, predicting health trajectories, and providing actionable clinical intelligence to optimize treatment protocols (Mirza *et al.*, 2025). DTx platforms function as digital extenders of clinical care teams rather than replacements, revolutionizing chronic condition management through technology (Rubinsztain, 2022). Moreover, these technologies help patients adhere to treatments, set viable care goals, and avoid costly emergency department visits and hospitalizations while enabling practitioners to streamline costs and monitor patient progress (Kaldy, 2020).

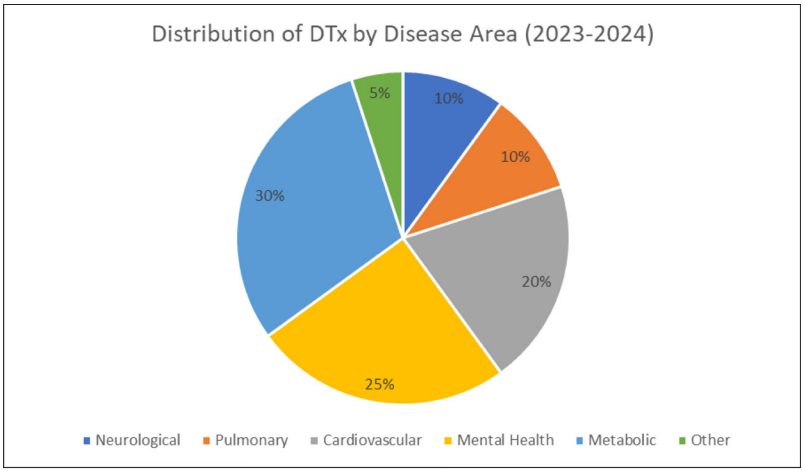


Figure 1: Distribution of Digital Therapeutics (DTx) Adoption across Disease Areas: Metabolic (30%), Mental Health (25%), Cardiovascular (20%), Pulmonary (10%), Neurologic (10%), Others (5%)

Table 1: Comparison between Digital Therapeutics (DTx), mHealth, and Telehealth

Factors	**Digital Therapeutics (DTx)**	**mHealth**	**Telehealth**	**Reference**
Purpose	Evidence based intervention delivered via software to prevent, manage and treat medical conditions	Health tracking, Fitness and data recording	Improving access for rural and isolated populations, ensuring safety during outbreaks, managing various disease and facilitating care for those with limited mobility	(Ali *et al.*, 2024; Anawade *et al.*, 2024; Chen *et al.*, 2021; Bouabida *et al.*, 2022; Wang *et al.*, *2023*; Zovi *et al.*, 2025)
Therapeutic Claim	Utilize randomized controlled trails (RCTs) for clinical validation, similar to conventional drugs, but may also employ real-world data and digital biomarker	Use of reminders, self-monitoring instruments and educational support to enhance medication management	Positive patient-centered outcomes, including adherence and satisfaction with care	(Duffy*et al.*, 2023; Ezeamii *et al.*, 2024; Huh *et al.*, 2022; Liquori *et al.*, 2024; Moulaei *et al.*, 2023)
Regulatory Approval Required	Regulated as software-as-a-medical-device (SaMD) byFood and Drug Administration (FDA)	must comply with various regulatory aspects to be classified as medical devices, specific guidelines for these applications are often lacking in current medical device regulations	Establishing physician-patient relationships, obtaining informed consent, and maintaining standard of care take on additional regulatory dimensions in telehealth	(Gupte *et al.*, 2025; Holfelder *et al.*, 2021; Jürgens *et al.*, 2024; Lakhan, 2025; Miao *et al.*, 2022)
Prescription Use	Yes-can be used	Prescription by apps	Prescription can be issued through telehealth	(Almeman, 2024; Brezing & Brixner, 2022; Byambasuren *et al.*, 2020; Johnson *et al.*, 2024; Salsabili *et al.*, 2023; Shafai & Aungst, 2023)
Technology Type	Software based to treat medical condition	Mobile apps and wearables	Telemonitoring by audio and video	Lee *et al.*, 2024; Morita, 2020; Shah & Shah, 2023; Wang *et al.*, 2023; Zoder-Martell wt al., 2020; Zovi *et al.*, 2025)

3. Mechanism of Action of Digital Therapeutics (DTx) in Chronic Disease

Digital Therapeutics (DTx) operates via an integrated triad of mechanisms, including behavior modification, algorithmically driven personalization, and integration into digital health care systems, that together offer meaningful management of chronic diseases. First, Digital Therapeutics (DTx) access behavioral change support systems (BCSS) to help users build habits progressively; users establish customized goals and receive real-time feedback, motivational messaging, game mechanics, and visual performance analytics to encourage new behaviors to stick, including patterns of healthy diet, regular physical activity, adherence to a medication schedule, and better sleep hygiene (Phan, Mitragotri, & Zhao, 2023; Yang *et al.*, 2025). Recent randomized trials demonstrated the significant impact of diabetes-focused mobile health (mHealth) platforms on patient outcomes, particularly in Asia. These interventions lead to improved glycemic control with reductions in HbA1c levels ranging from 0.49% to 1.25% (Ghose *et al.*, 2021). At the same time, Digital Therapeutics (DTx) harnesses advanced analytics and artificial intelligence (AI) to analyze and make sense of the huge data continuously generated by patients. Wearable bioelectronics allocate physiological (heart rate, activity levels, etc.) and biochemical signals, and algorithms with artificial intelligence (AI) system that information for earlier detection, personalized prediction, and adaptive therapy plans, so care goes from reactive to proactive (Huang *et al.*, 2025). Two such examples are glucose-monitoring wearables that are integrated with Digital Therapeutics (DTx) apps to deliver agile insulin reminders and behavioral nudges in detecting deviations for real-time interventions. Recent advancements in wearable health technology and electronic health record (EHR) integration are transforming patient care and clinical trials. EHR-integrated systems for remote symptom monitoring have been developed particularly in oncology, enabling real-time data collection and alerting (Zahedani *et al.*, 2023). These systems can enhance communication between patients and providers, potentially improving health outcomes. Digital pill diaries integrated into EHRs are being used to monitor chemotherapy adherence in decentralized clinical trials, allowing for continuous monitoring and timely interventions (Murthi *et al.*, 2024). From a visual standpoint, Digital Therapeutics (DTx) works through a work process that starts with patient inputs through behavior logs, sensor signals, and self-reports, which can then inform algorithms depending on the level of artificial intelligence (AI) involved and then produce custom intervention notifications, behavioral nudges, and adaptive therapy forwarding delivered through mobile interfaces. The digital feedback loop extends through user feedback, engagement data, and ongoing surveillance, facilitating iterative refinement of therapeutic content and timing of interventions. Digital Therapeutics (DTx) applies this approach to diabetes, depression, and other chronic conditions by combining behavioral support, predictive analytics, and ongoing monitoring: for example, individuals with DM2 using Digital Therapeutics (DTx)-enabled glucose sensors and artificial intelligence (AI) coaching reduce their HbA1c levels by ~0.4% over a year (Hu *et al.*, 2023). Digital Therapeutics (DTx) is emerging as an innovative intervention that leverages digital technologies to treat various conditions, particularly those related to lifestyle and behavior (Crisafulli *et al.*, 2022a; Vasdev *et al.*, 2024). Digital Therapeutics (DTx) offers a personalized, data-driven approach to healthcare, integrating artificial intelligence (AI) and machine learning for efficient clinical monitoring and patient engagement (Armeni *et al.*, 2024). While Digital Therapeutics (DTx) shows promise in advancing personalized medicine, its widespread adoption faces challenges such as regulatory hurdles, limited clinician training, and the need for post-marketing surveillance (Fassbender *et al.*, 2024).

4. Clinical Evidence and Outcomes

The clinical evidence for Digital Therapeutics (DTx) in chronic disease management has properly demonstrated their capacity to match and, in several cases, exceed traditional interventions. A major meta-analysis of randomized controlled trials quantifying the effect size across varied conditions reported a weighted average effect of 1.13 (95% CI: 0.91–1.36), indicating high therapeutic impact with low risk of bias (Bodner *et al.*, n.d.; Seo *et al.*, 2024). Definitely, in type 2 diabetes (T2MD), an analysis of app-based multimodal interventions following DiGA criteria was published in 2025 and reported a mean HbA1c reduction of 0.36% (95% CI –0.59 to –0.14; P<. 001) compared to usual care (Bodner *et al.*, n.d.). A further meta-analysis of 2022 demonstrated a standardized mean difference (SMD) of –0.49 in HbA1c and a slight drop in triglyceride (SMD = –0.18), but found no effect on blood pressure or cholesterol. Figure 2 visually depicts how different types of Digital Therapeutics (DTx) interventions contribute to HbA1c reduction, emphasizing that multimodal DTx models yield greater effectiveness than standalone apps, consistent with findings (J. E. Kim *et al.*, 2022). Maybenot all results are good: A 2025 Cochrane-style systematic review of 23 digital interventions targeting hypertension and diabetes found no differences for standard care in HbA1c, weight, depression, or hospitalizations, with the exception of mild improvement in systolic blood pressure, emphasizing the need for more robust study design and more profound integration (Ambrosi *et al.*, 2025). Aside from metabolic conditions, cardiovascular management via Digital Therapeutics (DTx) has potential in real-world use: a three-year JAMA trial of the Hello Heart hypertension application linked to a smart cuff found 84% of subjects with Stage II

hypertension experienced sustained blood pressure control (Chung, 2019). Recent studies demonstrated the effectiveness of digital mental health interventions in reducing depressive symptoms and suicidal ideation. Figure 4 illustrates how Digital Therapeutics (DTx) contribute across four major disease domains, showing mental health leading in overall impact, driven by robust clinical trials and higher patient engagement, compared to pulmonary diseases, where adoption remains in early stages. Table 2 consolidates evidence from multiple real-world and clinical studies across cardiovascular, metabolic, mental health, and pulmonary conditions, showing measurable patient outcomes like decreased HbA1c, improved blood pressure control, and enhanced quality of life. The Meru Health program, a therapist-supported smartphone app, showed significant reductions in depressive symptoms among patients with moderate to severe depression, with mean PHQ-9 score decreases of 7.3 points and effect sizes up to 1.7 (Forman-Hoffman *et al*., 2021a). Other studies have evaluated the efficacy of AKL-TO1 (EndeavorRX®), a Food and Drug Administration (FDA)-authorized digital therapeutic platform for attention in Attention-Deficit/Hyperactivity Disorder (ADHD) across different age groups. In adults with Attention-Deficit/Hyperactivity Disorder (ADHD), a 6-week trial showed significant improvements in attention metrics, with the change in TOVA-ACS nearly 7 times greater than those observed in pediatrics (Stamatis *et al*., 2024). When aggregated across meta-analyses, forest plot visualizations show modest but consistent beneficial effects of Digital Therapeutics (DTx) on primary outcomes, with the effects of different conditions and intervention maturities varying by the size of the effect. "Figure 3" compares standardized therapeutic effect sizes from meta-analytic data, demonstrating that behavioral health interventions show the highest effect sizes while metabolic interventions tend to produce more moderate outcomes, underscoring the need for standardization in metabolic DTx protocols. A large meta-analysis including chronic diseases, however, identified substantial benefits (effect size ≈1.1), particularly in software-based behavioral intervention. Nevertheless, a few digital health trials (not therapeutic, strictly speaking) have found no difference from usual care, and so the take-home message is mixed, emphasizing the importance of good digital trial design, including well-specified control arms and intervention standards. "Figure 3" (Ambrosi *et al*., 2025). Recent advancements in Digital Therapeutics (DTx) show their alignment with personalized medicine goals through the integration of artificial intelligence (AI) and real-time patient data. Artificial intelligence (AI)-driven Digital Therapeutics (DTx) enhances patient-centered approaches by providing tailored interventions, real-time monitoring, and predictive analytics (Jharbade, 2025). These technologies proceed with efficient clinical monitoring and supervision at the individual level for various diseases (Vasdev *et al*., 2024). A study published in 2023 in NPJ Digital Medicine showed that machine learning-based Digital Therapeutics (DTx) platforms for T2DM were able to automatically control dietary, physical activity, and medication reminders according to intra-day glycemic variability and user interaction, enabling a personalized intervention and a relatively significant drawing down in HbA1c relative to static protocols (mean difference –0.48%, $p<0.01$) (Mohsen *et al*., 2023). Recent studies have shown the effectiveness of artificial intelligence (AI)-powered cognitive behavioral therapy (CBT) chatbots in improving mental health outcomes. A systematic review found that Woebot, Wysa, and Youper significantly reduced symptoms of depression and anxiety, with high user engagement and satisfaction (Farzan *et al*., 2025). A randomized controlled trial of Therabot showed significant improvements in symptoms of major depressive disorder, generalized anxiety disorder, and eating disorders compared to a waitlist control (Heinz *et al*., 2025). Wysa, in particular, demonstrated effectiveness for users with chronic pain, showing greater engagement than users without chronic pain and significant improvements in PHQ-9 and GAD-7 scores (Meheli *et al*., 2022). Additionally, users reported a strong therapeutic alliance with Wysa, comparable to traditional CBT, with alliance scores improving over time. These findings suggest that artificial intelligence (AI) CBT chatbots can provide accessible and effective mental health support, complementing traditional therapy options (Beatty, Malik *et al*., 2022).

Table 2: Case Studies Presenting the Impact of Digital Therapeutics (Dtx) in Chronic Disease Management

Category	Disease Area	Intervention Type	Reported Outcomes	Reference
Cardiovascular Disorder	Hypertension Management	DTx interventions (Meta-analysis of 15 RCTs)	↓ Systolic BP by 3.75 mmHg; ↓ Diastolic BP by 1.79 mmHg compared to controls; 47% improvement in BP control rates	(Liu et al., 2025)
	Hypertension Management	HERB-DH1 pivotal trial	DTx systems reduced 24-hour ambulatory systolic BP by 2.4 mmHg vs standard lifestyle modification alone in patients not receiving antihypertensive therapy	(Kario et al., 2020)

Category	Disease Area	Intervention Type	Reported Outcomes	Reference
Cardiovascular Disorder	Hypertension Management	Real-world mobile BP self-management program	Sustained blood pressure control for up to 3 years in a cohort of 28,189 U.S. adults	(Gazit *et al.*, 2021)
	Hypertension Management	Meta-analysis of 18 telehealth-based studies	86% of participants achieved greater systolic BP reduction; 85% experienced improved diastolic BP compared to controls	(Kalagara *et al.*, 2022)
Mental Health	Depression	Meru Health Program (MHP), therapist-supported digital mental health intervention	Participants with PHQ-9 ≥ 15 showed PHQ-9 score reductions of 7.3–8.3 points, maintained up to 12 months post-intervention. A 12-week enhanced MHP version showed (d = -0.8 vs waitlist), with a higher proportion achieving clinically meaningful improvement. One trial in young adults showed no difference except in those on antidepressants	(Forman-Hoffman *et al.*, 2021b)
	ADHD (Attention-Deficit or Hyperactivity Disorder)	AKL-T01 (EndeavorRx®), FDA-authorized DTx	Adults (n = 153): TOVA-ACS scores improved by 6.46 points (7× greater than pediatric change); higher compliance (81.8%), minimal adverse events (5%). Adolescents (age 13–17): TOVA-ACS improvements of 2.6 points over 4 weeks. Across trials, cognitive performance data correlated with improved clinical outcomes and quality of life	(Stamatis *et al.*, 2024)
Pulmonary Disorder	COPD	EASYBREATH app, randomized controlled trial	+57.68 m increase in 6-minute walk distance vs +21.71 m in controls after 8 weeks; significant improvements in dyspnea, CAT scores, and quality of life measures	(C. Kim *et al.*, 2024a)
	COPD	Meta-analysis of mobile app-based pulmonary rehab	Statistically significant improvements in CAT scores (mean difference = -1.29) compared to conventional rehab	(Ora *et al.*, 2022)
	COPD	Kaia COPD app	Maintained physical activity levels post-pulmonary rehab; intervention group showed significantly better step counts and improved CAT scores at 6 months	(Spielmanns *et al.*, 2023)
	Chronic Respiratory	Digital interventions	Offer accessible, time-efficient alternatives to center-based programs, especially relevant for post-COVID patients with similar symptom profiles	(Rinn *et al.*, 2023)

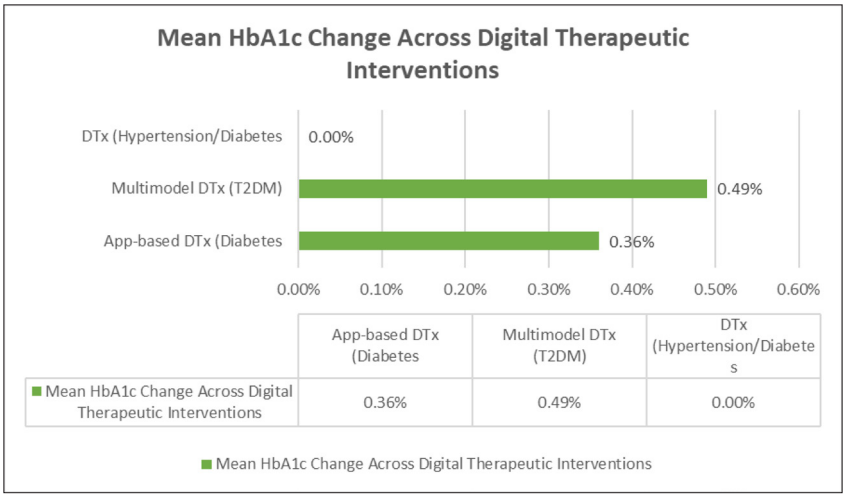


Figure 2: Average HbA1c reduction by Digital Therapeutics (DTx) Intervention Type in T2DM: Multimodal DTx (-0.49%) and Standalone App-Based DTx (-0.36%)

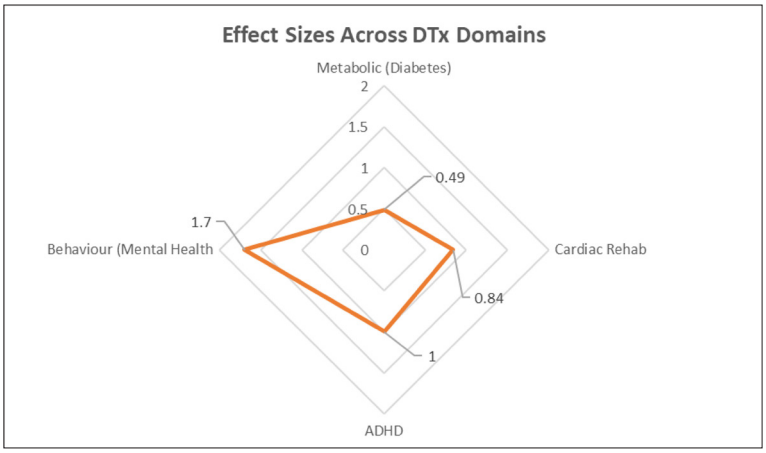


Figure 3: Standardized Effect Sizes of Dtx by Disease Domain: Behavioral (1.7), Cardiac (0.84, ADHD (0.49), Metabolic (0.36-0.49).

5. Therapeutics Applications by Disease Area

Digital Therapeutics (DTx) are essential in chronic disease management, delivering personalized, software-driven interventions through different medical conditions. Their effect is scalable in the ground of cardiovascular, metabolic, mental health, and pulmonary disorders and is supported by clinical data and real-world outcomes. Digital Therapeutics (DTx) systems that communicate with smartphone apps, wearables, and cloud analytics have been improved to substantially enhance lifestyle change, medication adherence, and physiological factors. A meta-analysis of 26 experiments with 2,576 subjects reported meaningful decreases in BP, changes in lipid profile, and increased PA levels (see Figure 4; Table 2).

5.1. Cardiovascular Disorder (CVD)

In cardiovascular disease (CVD), Digital Therapeutics (DTx) systems that communicate with smartphone apps, wearables, and cloud analytics have been developed to substantially improve lifestyle change, medication adherence, and physiological factors. A meta-analysis of 26 experiments with 2,576 subjects reported meaningful decreases in BP, changes in lipid profile, and increased PA levels (Huh *et al.*, 2022). A long-term remote monitoring program for stage II hypertension patients across multiple U.S. healthcare facilities showed substantial blood pressure improvements, with higher adherence linked to greater reductions (Subramanian *et al.*, 2024). Furthermore, digital CR programmes have demonstrated better exercise capacity and quality of life versus CR programmes with face-to-face elements (Prabhughate & Gharat, 2024). Researchers caution that many studies have small sample sizes and insufficient long-term follow-up, especially in underrepresented communities in countries like rural India. The field is trending towards artificial intelligence (AI)-based diagnostics (cardiac digital twins, automated ECG) that would enable more advanced personalization, but there is still a need for validation protocols (Naik *et al.*, 2025).

5.2. Metabolic Disorder

With T2DM, Digital Therapeutics (DTx) interventions such as continuous glucose monitoring (CGM)-enabled apps/ lifestyle-coaching tools are showing moderate effects, yet clinically significant reductions in CGM-induced glycemic control. In a systematic review (2025), CGM strategies reduced HbA1c over a range of follow-up periods (Asif & Gaur, 2025). Moreover, one randomized field experiment in 2021 in Asia, including 1,070 patients, revealed enhanced dietary/exercise behaviors and lower blood glucose with a mobile platform (Ghose *et al.*, 2021). A recent meta-analysis showed the efficacy of Digital Therapeutics (DTx) in managing chronic conditions. For T2DM, Digital Therapeutics (DTx) interventions led to significant reductions in HbA1c with improvements ranging from –0.30% to –1.08%. Weight loss outcomes were also notable, with studies reporting reductions of 0.63 kg to 6.84 kg (Kannenberg *et al.*, 2024a; Michaud *et al.*, 2021).

5.3. Mental Health

Recent studies demonstrated the effectiveness of digital mental health interventions combining artificial intelligence (AI) and human support. A therapist-support mobile health program showed significant reductions in depressive symptoms for patients with moderate to severe depression. A digital intervention using an AI-driven conversational agent with human oversight achieved comparable outcomes to face-to-face therapy for anxiety, while significantly reducing clinician time (Forman-Hoffman *et al.*, 2021a; Palmer *et al.*, 2025). Another study reported similar results, with the digital program showing non-inferiority to traditional CBT. A systematic review of AI-powered CBT chatbots revealed large improvements in mental health symptoms

across multiple platforms, with high user engagement and satisfaction (Farzan *et al.*, 2025). Its application has shown promising results in managing Attention-Deficit/ Hyperactivity Disorder (ADHD) symptoms, particularly in children and adolescents. A meta-analysis of 31 studies found that digital interventions improved inattention symptoms, decreased reaction time, and enhanced executive function and working memory in ADHD patients (He *et al.*, 2023). The FDA-approved EndeavorRx and other digital interventions have demonstrated improvements in processing speed, distractibility, and core ADHD symptoms (Zhao *et al.*, 2024). An estimated 970.1 million people worldwide had a mental or substance use disorder in 2019, equivalent to 1 in every 7–8 persons, and contributing an estimated 13% of the total global burden (Allison *et al.*, 2023).

5.4. Pulmonary Disorder

In chronic respiratory diseases such as COPD, Digital Therapeutics (DTx) improve self-management with the help of integrating educational content, symptom trackers, and environmental alerts. A meta-analysis in the Journal of Medical Research including 11,000+ patients showed specific improvements in quality-of-life scores (CAT, EQ-5D) at 3–12 months, though mixed effects on objective outcomes like hospital admissions (Alastair Watson & Wilkinson, 2022; Zhuang *et al.*, 2025). In an RCT with the EASYBREATH pulmonary rehab app, participants gained clinically meaningful improvements in 6-minute walk distance, with approximately a 57 m increase compared with 21 m in the control group, and improved symptom scores after 8 weeks (C. Kim *et al.*, 2024). Further innovations such as smart inhalers also detect early exacerbation signals via data on respiratory patterns and pollution exposure (Alastair Watson & Wilkinson, 2022). The prevalent mental disorders are depression and anxiety; there is an estimated 4–5% of the adult population in the world suffering from depression and anxiety disorders, which are also particularly highly prevalent (Moitra *et al.*, 2023). Post-Traumatic Stress Disorder (PTSD) has a lifetime prevalence of 3.9%, with prevalence rates for ADHD estimated at 6–7% in children and 2.5% in adults, according to meta-analytic and epidemiologic reviews (Gelner *et al.*, 2023). Table 3 below shows comparative study of disease-specific digital therapeutics (DTx) case studies.

Table 3: Comparative Study: Disease-specific Digital Therapeutics (DTx) Case Studies

Disease Area	Intervention Type	Reported Outcomes	References
Cardiovascular Disorder	Apps, wearables, remote monitoring, and digital CR	↓ BP, ↑ exercise capacity, ↑ quality of life	(Huh *et al.*, 2022; Prabhughate & Gharat, 2024)
Metabolic Disorder	CGM-enabled apps, coaching tools, and mobile platform	↓ HbA1c (–0.30% to –1.08%), ↓ weight (0.63–6.84 kg)	(Kannenberg *et al.*, 2024a)
Mental Health	Artificial intelligence (AI)-driven therapy, CBT chatbots, human-AI supports	↓ Anxiety and depression symptoms, comparable to CBT	(Farzan *et al.*, 2025; Forman-Hoffman *et al.*, 2021a)
Pulmonary Disorder	Educational content, symptom trackers, and smart inhalers	↑ QoL scores (CAT, EQ-5D), ↑ 6MWD (+57 m), ↓ exacerbations	(Alastair Watson & Wilkinson, 2022)

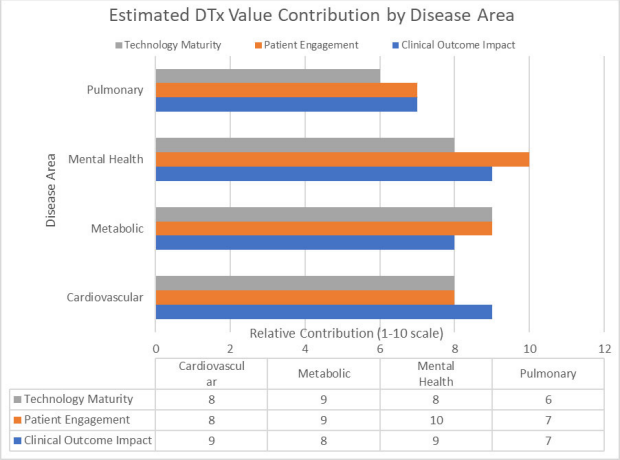


Figure 4: Comparative Contribution of Dtx across Disease Domains based on Clinical Outcomes and Patient Engagement: Mental Health > Cardiovascular Metabolic > Pulmonary

6. Regulatory Landscape and Policy Framework

The regulatory and policy ecosystem surrounding Digital Therapeutics (DTx) spans diverse jurisdictions and is evolving rapidly. As market-ready Digital Therapeutics (DTx) expand, nations must address oversight, reimbursement, and integration into care systems to ensure coverage, quality, and ethical deployment. The Food and Drug Administration (FDA)'s Digital Health Center of Excellence (DHCoE), established within CDRH in 2020, has quickly become a central authority for the regulation of Software as a Medical Device (SaMD) and artificial intelligence/machine learning (AI/ML)-driven products. It has now included over 700 AI/ML-enabled medical devices that have been authorized for marketing in the U.S. (Zhu *et al.*, 2022).

Prescription Digital Therapeutics (PDTs) are FDA-regulated, software-based treatments delivered via mobile devices, offering evidence-based therapies for various conditions. These technologies are rapidly evolving, outpacing current FDA regulatory processes and necessitating a better understanding of their evaluation and approval (Brezing & Brixner, 2022). Between 2017 and 2025, over 35 PDTs were cleared by the FDA, targeting conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD), insomnia, Post-Traumatic Stress Disorder (PTSD), and major depressive disorder. These PDTs undergo rigorous evaluation through established pathways like De Novo and 510(k). The regulatory landscape for PDTs is evolving, with varying labeling language and therapeutic claims (Brezing & Brixner, 2022; Xia *et al.*, 2025).

The Breakthrough Device Program (BDP) in the U.S. aims to accelerate medical device approvals with median review times of 152 days for 510(k), 262 days for De Novo, and 230 days for PMA devices. These timelines are significantly faster than standard approvals. However, only 12.3% of BDP-designated devices received marketing authorization from 2015–2024 (Gupte *et al.*, 2025). The FDA is refining its regulatory approach to AI/ML-based Software as a Medical Device (SaMD) through initiatives like the AI/ML Action Plan and a draft framework for managing software modifications. These efforts emphasize real-world performance monitoring and bias mitigation (Carolan *et al.*, 2022).

Even with maximum approvals, recent analyses by outlets like **STAT News** and RAPS have raised lingering concerns: gaps in evidence from pivotal trials, anemic post-market surveillance, and adherence to statutory timelines. These analyses highlight that approximately 12% of breakthrough-designated devices were recalled, sometimes with weak post-market follow-up (Kadakia *et al.*, 2025).

Digital Therapeutics (DTx) are emerging as promising medical interventions in Europe, but their adoption and reimbursement remain fragmented across countries. Germany's DiGA Fast-Track system, established under the Digital Healthcare Act in 2019, has enabled over 374,000 DTx prescriptions and serves as a model of integration (Schmidt *et al.*, 2024). Other European nations are developing similar frameworks, with France working on a fast-track system for DTx reimbursement (Mantovani *et al.*, 2023). However, significant differences exist in assessment criteria, with emphasis on product positioning, comparators, and usability data.

Challenges to widespread adoption include a lack of harmonization in regulatory requirements, sociodemographic factors, ethical concerns, and limited awareness among healthcare professionals and patients (Arcà *et al.*, 2025). The evolving regulatory landscape, including the EU's Medical Devices Regulation and In Vitro Diagnostic Regulation, aims to address these issues and potentially establish a more harmonized framework for DTx assessment and integration (Arcà *et al.*, 2025; Mantovani *et al.*, 2023).

The German Digital Health Application (DiGA) system, introduced in 2019, allows for reimbursement of digital health apps in statutory health insurance. As of mid-2024, 56 DiGA were listed, with 35 permanently and 21 provisionally approved (Goeldner & Gehder, 2024; Schliess *et al.*, 2024). The fast-track process enables provisional reimbursement while gathering evidence of positive healthcare effects (Gensorowsky *et al.*, 2022). Belgium, France, and the U.K., on the other hand, require the CE mark but have markedly different HTA and reimbursement systems (Mäder *et al.*, 2023).

Belgium has an mHealth pyramid requiring CE certification, data protection, interoperability, and clinical evidence for third-tier reimbursement (Lievevrouw *et al.*, 2024; Schudt *et al.*, 2022). France's CNEDiMTS and HAS rating for added benefits (ASA scale I–IV) and the PECAN fast-track system support early funding. Moovecare Pulmon received reimbursement (approximately €500/quarter) (Martin *et al.*, 2024).

China leads in approved applications (235), followed by the U.S. (192) as of mid-2025 (Liang *et al.*, 2025). In China, DTx primarily focuses on neurological and ophthalmic indications that utilize computerized cognitive correction (Jiang *et al.*, 2025). Japan has made progress in digital health initiatives, with two cardiovascular DTx applications approved and reimbursed by mid-2023 (Nomura, 2023).

India's regulatory concern for DTx is emerging and primarily builds on broader digital health initiatives of the Government of India, with no specific guidelines for the regulation of DTx. Software as a Medical Device (SaMD) is regulated by the Central Drugs Standard

Control Organization (CDSCO) under the Medical Device Rules, 2017, while DTx is currently placed under a generic category without clear classification (Acosta, 2025). The Ayushman Bharat Digital Mission (ABDM), launched in 2021, aims to establish a national digital health ecosystem in India. It builds on the Ayushman Bharat Program, which includes Health and Wellness Centers to strengthen primary healthcare (Lahariya, 2020; Sharma *et al.*, 2023).

The ABDM creates digital public goods and uses an interoperable framework, open protocols, and consent artifacts to enable stakeholder collaboration and equitable healthcare digitalization. This aligns with global efforts to leverage technology in healthcare, as exemplified by the Fast Health Interoperability Resource (FHIR) standard, which facilitates electronic health record interoperability. Figure 5 shows the timelines of major regulatory approvals and policy milestones that have shaped the evolution of DTx, underscoring the accelerated adoption of frameworks like the FDA's Software as a Medical Device (SaMD) and Germany's DiGA system (Ayaz *et al.*, 2021; Sharma *et al.*, 2023).

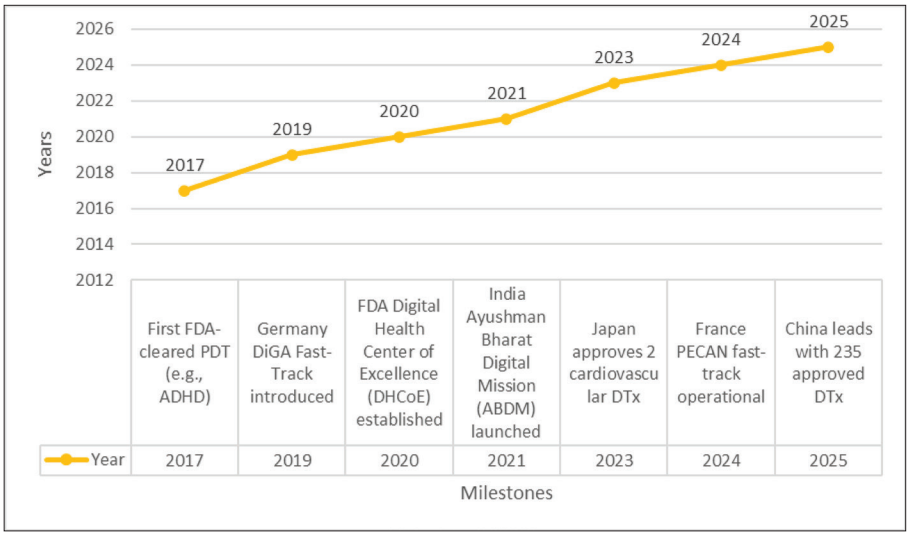


Figure 5: Timeline of Major Digital Therapeutics (DTx) Approvals and Regulatory Milestones

7. Future of Digital Therapeutics (DTx) in Multidisciplinary Healthcare Systems

The future of Digital Therapeutics (DTx) is being defined by innovations in artificial intelligence (AI) and machine learning (ML), which will power next-generation platforms that can personalize in real-time, intervene adaptively, and connect more deeply to the patient experience. Precision health architectures that leverage digital biomarkers and closed-loop clinical feedback are enabling dynamic, real-time treatment modification, further optimizing software-based treatments (Palanica *et al.*, 2020; Vasdev *et al.*, 2024).

Recent scoping reviews have highlighted the growing application of ML in health promotion and behavioral change interventions. ML techniques have shown potential in optimizing health outcomes, personalizing interventions, and improving adherence (Goh *et al.*, 2022). Meanwhile, reinforcement learning is being investigated to optimize the timing, dosage, and sequence of delivering digital interventions, suggesting the direction of travel towards fully adaptive DTx systems (Deliu & Chakraborty, 2024).

Integration with wearables, smart-home systems, and real-time monitoring devices further enhances the ability of DTx platforms to capture biometric signals in near-continuous mode—such as glucose, ECG, and respiratory data—and to ingest and process these measurements in AI algorithms to generate instant feedback or alarms. One market analysis explained that continuous biometric feedback is a game-changing aspect of next-generation DTx apps addressing diabetes, cardiovascular disease (CVD), and pulmonary issues (Vasdev *et al.*, 2024).

Smart-home technologies offer promising solutions for supporting older adults' independent living and managing chronic conditions. AI-driven predictive analytics represent a transformation in chronic disease management by enabling early detection and proactive interventions before clinical symptoms emerge. These systems analyze vast datasets from electronic health records (EHRs), genomics, lifestyle data, and real-time biosensors to identify subtle patterns indicative of disease onset (Kamal *et al.*, 2021; Mia Md Tofayel Gonee Manik, 2021).

AI-driven early warning systems show significant promise in predicting patient health deterioration using large-scale,

real-time data from EHRs, wearable devices, and physiologic monitors. These systems leverage advanced ML techniques, including recurrent neural networks, convolutional neural networks, and ensemble methods, to analyze sequential patient data and identify patterns indicative of clinical deterioration before it becomes overt (Arsalan, 2025). These systems can integrate environmental sensors, voice interfaces, and mobile apps to monitor health, detect emergencies, and provide personalized care (Colnar *et al.*, 2020; Facchinetti *et al.*, 2023).

Artificial Intelligence (AI) offers promising solutions for various patient populations, including those with rare diseases. AI-based systems can improve diagnosis, treatment, and monitoring of rare diseases by providing personalized, clinically approved tools that adapt to a patient's changing condition (Hurvitz *et al.*, 2021). For pediatric patients, gamified DTx can enhance engagement and adherence, while for the elderly population, such tools can improve compliance and safety (Wojtara *et al.*, 2023).

New advancements in personalized medicine are transforming chronic disease management by integrating genetic screening and pharmacogenomics to control treatments (Sugandh *et al.*, 2023). However, communicating precision medicine faces challenges in data integration and management, requiring efficient computational approaches to handle heterogeneous datasets while adhering to ethical constraints (Martínez-García & Hernández-Lemus, 2022).

Digital transformation leveraging wearable sensors, AI, and the Internet of Medical Things (IoMT) is poised to accelerate personalized medicine by enabling real-time phenotyping and digital clinical trials (Lin & Wu, 2022). Emerging technologies such as nanoparticles for drug delivery, AI-guided drug dosing, and genome editing platforms are driving advances in precision medicine. These innovations aim to optimize combination therapies and individualize patient care from diagnosis through treatment. However, widespread deployment requires addressing factors like medical education, clinical trial designs, and scaling electronic medical records (Ho *et al.*, 2020).

Furthermore, in the era of personalized medicine currently being pursued by healthcare systems globally, DTx is playing a key subsidiary role in solving some of the most challenging problems. Classical drugs, which are not personalized, face limitations in prescribing and individualized treatment due to lack of access to genetic information, well-informed clinical decision-making, and real-time patient monitoring. AI-enabled DTx platforms, however, use digital biomarkers and behavioral analytics to provide dynamically personalized interventions, effectively serving as a phenotypic proxy in the absence of genomic machinery. This, in turn, allows in-the-moment personalization of medicines for conditions such as diabetes, hypertension, and mental health.

AI and ML woven into DTx can continually evolve personalized response patterns, driving higher engagement, adherence, and clinical success—in stark contrast to static prescribing models at scale (Bolpagni *et al.*, 2024).

8. Challenges

While Digital Therapeutics (DTx) have the potential to transform how healthcare is delivered to patients, several challenges exist at the ground level—especially in low-resource and/or low- and middle-income country settings, including India—that continue to hamper adoption, trust, and scalability.

AI-enhanced Digital Therapeutics (DTx) represent a transformative concept in healthcare delivery, particularly for chronic disease management. DTx are clinically validated, software-based therapeutic interventions that leverage AI technologies, including machine learning and advanced data analytics, to increase efficacy, personalization, and scalability (Shin *et al.*, 2024).

The digital divide significantly impacts healthcare access, especially affecting rural populations, older adults, and those with limited digital literacy. Rural communities face barriers including limited high-speed internet access, higher service costs, and underdeveloped information and communication technologies, resulting in lower digital health literacy (Sui & Facca, 2020a).

Additionally, there is a deficiency in patient safety monitoring—fewer than 25% of DTx platforms incorporate safety escalation mechanisms to manage urgent clinical events—which increases ethical concerns and decreases clinical trustworthiness (Mennella *et al.*, 2024). For healthcare providers, awareness and adoption among clinicians remain extremely low. Digital Therapeutics (DTx) showcase an emerging concept of software-based medical interventions that utilize algorithms to treat, manage, and prevent various diseases and disorders. Despite their significant therapeutic potential, DTx adoption remains in preliminary stages due to several challenges, including regulatory hurdles and limited physician uptake (Armeni *et al.*, 2024).

In the Indian healthcare context, DTx show particular promise for heart failure management, offering solutions for medication adherence, remote monitoring, patient education, and timely interventions through dedicated teams of cardiologists and health coaches (B. Singh *et al.*, 2023). Research confirms that infrastructure limitations pose particular challenges to AI integration in healthcare systems, especially in developing countries. Fragmented electronic health records (EHRs) and poor interoperability present major barriers to AI-powered DTx implementation (Mwogosi & Mambile, 2025; V. Sharma *et al.*, 2021).

One key issue is health literacy and patient education in the digital environment. Studies find a wide digital divide among rural Indian populations, particularly among older adults and women, who often lack the skills or comfort to use smartphones or health apps. Programs like PMGDISHA have made some progress, but the literacy divide remains high, particularly due to the absence of language localization and culturally appropriate interfaces (Nedungadi *et al.*, 2018; Patel *et al.*, 2024).

Closely related to this is patient safety and monitoring of undesirable drug effects. Unlike pharmaceuticals, most DTx lack sophisticated, embedded systems for detecting and reporting safety issues in real-world settings. It has been revealed that less than 25% of platforms incorporate safety monitoring or escalation processes for urgent clinical events—a gap that threatens clinical trustworthiness and entails ethical risks (Denecke *et al.*, 2023).

Low physician resources and limited clinical acceptance are also barriers to integration. In India, a 2024 study identified that less than 1% of primary care physicians are aware of DTx as a prescribable solution, noting the absence of formal training and regulatory clarity. Without clinician recommendations, however, DTx continue to struggle for acceptance as standard care (Getov *et al.*, 2025).

From a policy standpoint, reimbursement and funding are key system-level problems. For instance, Germany has a functioning reimbursement structure for DTx (e.g., the DiGA system). The Indian policy ecosystem is progressing toward clarity via the intersection of a DTx policy and the Ayushman Bharat Digital Mission (ABDM), but has not yet formalized reimbursement processes or definitions for DTx as medical devices (Denecke *et al.*, 2023).

Political and infrastructural limitations also have important effects. Low internet penetration, siloed EHR systems, and low interoperability hinder the complete integration of AI-powered DTx across devices. These technical limitations restrict opportunities for personalization and predictive analytics (Sindakis & Showkat, 2024).

Furthermore, the objective of precision medicine faces challenges under multiple Indian realities. While DTx can use behavioral, sensor, and utilization patterns to approximate personalization, without population-level genomic data and standardized phenotype-associated trial protocols, they remain limited in precision (Recchia & Gussoni, 2023).

There are also challenges in the area of human prescription behavior. Unlike most drug dosing, prescriptions in DTx can take the form of flexible digital prescriptions that include dosing substitutes (e.g., sessions per week, notifications, or content steps) as well as adaptive arrangements of content. Physicians' familiarity with digital prescribing is low, and digital prescription practices are not consistent with policy or adequately integrated into the medical education system.

Lastly, ethical and privacy issues remain unresolved. There are no GDPR- or HIPAA-like comprehensive data protection laws in India, leaving the digital space prone to data misuse. Additionally, many AI algorithms inside DTx tools have been developed using non-Indian populations, raising concerns about cultural sensitivity and ethnic diversity bias (Phan *et al.*, 2023).

DTx face significant implementation challenges in addressing healthcare disparities, particularly among underserved populations. Research in rural India shows critically low digital literacy rates, with only 11% of older adults demonstrating proficiency with digital devices and less than 10% using them for health-related activities. Barriers include limited smartphone ownership (about 50% mobile phone ownership but minimal smartphone usage), poor traditional literacy, and age-related physical limitations such as vision problems. Rural populations face additional challenges, including limited high-speed internet access and underdeveloped information communication technologies, creating a substantial digital divide (Rasekaba *et al.*, 2022; Sui & Facca, 2020b).

Widespread clinical adoption remains limited due to multiple barriers. A critical challenge is the general lack of education among healthcare professionals, creating a knowledge gap between data scientists and physicians who should identify clinical applications of DTx (Crisafulli *et al.*, 2022b).

DTx platforms show significant promise for managing chronic diseases through personalized, evidence-based interventions. These systems demonstrate substantial clinical improvements, particularly in diabetes and cardiovascular management. AI-driven DTx platforms incorporating continuous glucose monitoring have achieved HbA1c reductions of 0.67% overall and 1.08% in poorly controlled diabetes patients, with 33% achieving near-remission status (Kannenberg *et al.*, 2024). By integrating with smart-home systems and wearable devices, DTx can provide near-continuous health monitoring and timely, personalized feedback to patients, thereby reducing reliance on in-person visits, which are often limited in rural areas (Armeni *et al.*, 2024).

9. Conclusion

Expanding on a set of cutting-edge global data reviews and practice models like the Food and Drug Administration (FDA), Software as a Medical Device (SaMD) axis, and India's Ayushman Bharat Digital Mission (ABDM), this review assesses Digital Therapeutics (DTx)'s capacity to close health gaps through precision medicine and behavioral interventions. As the worldwide DTx market is estimated to

reach approximately $56 billion by 2035, this text concludes with the strong need for interdisciplinary cooperation to leverage their full potential.

The convergence of clinical expertise, technological advancement, and health system integration firmly anchors Digital Therapeutics (DTx) as a fundamental element of future-ready chronic disease management. This review showed that while already established in high-income countries, DTx's potential lies in democratizing global healthcare access. Integration of DTx with AI, wearables, and Electronic Health Records (EHRs) paves the way for personalized and preventive care, especially benefiting vulnerable populations such as rare disease patients, and pediatric and geriatric groups.

Going forward, standardizing global regulations—including those from the FDA, the European Medicines Agency (EMA), and the Pharmaceuticals and Medical Devices Agency (PMDA)—will be essential for safe, effective, and scalable DTx growth. The success of future DTx also depends on real-world evidence (RWE) generation and strong post-market surveillance to track long-term efficacy and user adherence. It is equally important to ensure equitable access, meaning that the delivery of care through DTx platforms should be designed inclusively, with attention to disparities in digital literacy and adaptations to various socioeconomic and cultural circumstances.

Pairing DTx with genomics and AI-based dosing algorithms further advances the field toward true personalized medicine. As data continue to grow, ethical considerations regarding patient privacy, informed consent, and digital rights must evolve simultaneously. Additionally, with lower reliance on physical healthcare infrastructure, DTx offers potential to drive sustainable, low-carbon healthcare systems worldwide.

The integration of AI-driven DTx with Electronic Health Records (EHRs) represents a transformative advancement in healthcare delivery. AI-powered DTx platforms utilize machine learning, natural language processing, and computer vision to process patient data in real time, predict health trajectories, and deliver personalized interventions (Mirza *et al.*, 2025). The combination of AI with EHR systems enables healthcare providers to derive meaningful insights from large volumes of health data, supporting more informed decision-making through sophisticated algorithms that review patient histories, detect trends, and forecast outcomes with high accuracy (Gorrepati, 2024).

Electronic Health Record (EHR) and e-prescribing systems face significant implementation challenges despite their potential benefits. In Australian community pharmacies, 67% of pharmacists reported usability and efficiency issues with EHR systems, while 58% experienced delays from slow software performance and 42% encountered data transmission errors (Hareem *et al.*, 2024). In low-resource settings like India, the lack of standardized digital therapeutics guidelines and regulatory clarity further hinders adoption. Moreover, concerns over data privacy and the absence of comprehensive protections analogous to GDPR or HIPAA in India expose systems to potential misuse (Jain, 2023).

Abbreviations

DTx: Digital Therapeutics; **CVD**: Cardiovascular Disease; **AI**: Artificial Intelligence; **PTSD**: Post-Traumatic Stress Disorder; **FDA**: OIN; **SaMD**: Software as a Medical Device; **ABDM**: Ayushman Bharat Digital Mission; **ADHD**: Attention-Deficit/Hyperactivity Disorder

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Declaration

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