Opinion:

Beyond the Hype: Digital Therapeutics Delivering Personalised Healthcare

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Digital therapeutics are transforming healthcare by turning smartphones and wearables into personalised treatment tools, breaking down access barriers, and proving what real-time data can deliver. Better outcomes—anytime, anywhere.

THE RISE OF DIGITAL THERAPEUTICS

The widespread adoption of smartphones and wearable devices has created fertile ground for digital therapeutics (DTx), a technology-driven approach to managing patient health, particularly for chronic conditions and mental health. DTx enables continuous health monitoring together with real-time data analysis, which facilitates personalised healthcare solutions and interventions, thus improving patients' awareness and outcomes.

Additionally, DTx facilitates patient-centered care by transcending geographic boundaries and addressing limitations in healthcare resources, accessibility barriers, and provider availability, ultimately improving patient outcomes and alleviating strain on the healthcare system.

The introduction of DTx into the healthcare mainstream is facilitated by a maturing set of regulations that acknowledge and authorise these technologies. In combination with the newfound data on clinical outcomes that the era of DTx has ushered in, this also serves to validate and normalise its role in the healthcare ecosystem.

What is Digital Therapeutics?
Digital therapeutics are software-based treatments designed to prevent, manage, or treat diseases or medical conditions. In contrast to regular telehealth videocall software, DTx products are developed and clinically validated, and in most cases, considered as medical devices. They enhance the scope of telehealth practice by using different approaches such as mobile applications, wearables, VR or interactive platforms to present evidence-based therapeutic content to the patients and elicit specific behaviors.
DTx equip patients with monitoring tools that provide personalised treatment plans and establish feedback mechanisms, enabling patients to manage their health conditions effectively. DTx products are radically changing the healthcare sector by providing a higher level of care accessibility, engaging patients in self-care activities and enhancing medication compliance.

THE GROWING MARKET AND ESTABLISHED EVIDENCE

The digital therapeutics market has experienced remarkable growth, attracting significant investment over the past decade. While 2021 marked a peak with a total investment of nearly $60 billion[1], the market continues to show robust momentum[2]. This sustained capital growth highlights the growing recognition of DTx's value proposition and their potential to transform healthcare, captivating the attention of stakeholders across the industry.

The growing burden of behavioural health, mental health, dementia, and chronic illnesses challenge millions, and the magnitude of this challenge is staggering. The current healthcare landscape often falls short in providing multifaceted care and addressing complex long-term behavioral and mental health needs. One of the main barriers is the shortfall of continuous support and multifaceted approach needed for these conditions. Mental and behavioral health challenges require ongoing monitoring and self-management strategies. Traditional therapy sessions, while crucial, often lack the frequency needed to provide this continuous support. The gap between clinical visits can leave individuals vulnerable to setbacks and struggling to maintain progress. This gap can be closed with high-quality digital therapeutics, generating massive value for healthcare systems.

Behavioral and Mental Health
Over 1 billion people worldwide are affected by mental or behavioral health issues, with approximately 20% of adults in the United States experiencing mental illness annually[3-5]. Digital therapeutics offer significant benefits by helping individuals identify triggers, develop coping strategies, and set personalised goals. Features such as progress tracking, interactive content, and real-time feedback enhance user engagement and management of their conditions.

Clinical studies indicate that these digital interventions can substantially improve outcomes compared to traditional approaches. Moreover, there are continually emerging needs and opportunities in this field that merit further exploration.

Dementia
The global dementia population is exploding, with an estimation of over 55 million cases internationally in 2023[6]. This growing crisis creates a substantial market need for innovative solutions. Digital therapeutics offer scalable tools to support caregivers, stimulate cognitive function, and improve communication within the care network. As investment rises and clinical evidence mounts, the market for digital therapeutics in dementia management is poised for significant growth.

Treatment Adherence
Non-adherence to medication and treatment plans is a major clinical challenge in chronic disease management, leading to poor outcomes and increased healthcare costs, including an estimated 125,000 preventable deaths and up to $300-billion annually in avoidable healthcare costs in the US.

Digital therapeutics offer powerful tools that address this issue, including:

- Enhancing patient engagement
- Supporting long-term behavioural change
- Medication reminders
- Personalised education
- Progress tracking
- Gamification

CHALLENGES OF DIGITAL THERAPEUTICS

"Digital therapeutics hold immense promise, but demonstrating their impact can be trickier than with traditional drugs."

Unlike medications with immediate physiological effects, the effects of DTx often manifest subtly and gradually, influenced by a complex interplay of behavioural, environmental, and even social factors. Designing studies that convincingly demonstrate DTx efficacy requires innovative approaches.
Adaptive trial designs, long-term follow-up, and the

use of relevant surrogate endpoints can help capture these slower-burning effects. This inherent complexity makes it challenging to design studies that convincingly demonstrate their efficacy, particularly within the traditional evidence-based frameworks that regulators and healthcare professionals rely on.

The German DiGA program, while pioneering in its approach to DTx reimbursement, has also highlighted the difficulties in assessing and validating these novel interventions[7]. Concerns regarding the perceived low effectiveness and insufficient evidence for certain DiGAs, especially those provisionally listed, underscore the need for innovative trial designs and robust outcome measures.

> **Ensuring secure data storage, transmission, and strict adherence to privacy regulations like HIPAA and GDPR is of paramount importance**

To navigate these complexities, innovative approaches must be adopted. Adaptive trial designs, allowing for modifications during the study based on emerging data, can optimise the evaluation of DTx interventions. Long-term follow-up studies are essential to capture the sustained impact of DTx, as their benefits often unfold over extended periods. Furthermore, leveraging relevant surrogate endpoints, which are measurable indicators that predict clinical outcomes, can provide valuable insights into the effectiveness of DTx, even when direct clinical endpoints are challenging to assess.

Additionally, establishing a clear and quantifiable link between DTx interventions and specific biological changes is another hurdle and requires sophisticated research. Unlike traditional pharmaceuticals, where the impact on biological pathways is often more evident, attributing a desired outcome solely to a DTx intervention is inherently complex. This complexity can make it difficult to gain acceptance from regulators and healthcare professionals who traditionally rely on biological mechanisms to validate treatments. The expansion of Germany's DiGA program to include higher-risk medical devices further raises the bar for evidence standards, necessitating rigorous studies, such as prospective comparative trials[7]. Developing robust biomarkers, which are biological indicators of disease or treatment response, can help bridge this gap and provide tangible evidence of DTx's impact on the underlying biological processes. Finally, the vast amount of personal health data collected by DTx raises a dual challenge: safeguarding patient privacy while harnessing the potential of real-world data (RWD) and evidence (RWE). Ensuring

secure data storage, transmission, and strict adherence to privacy regulations like HIPAA and GDPR is of paramount importance. Any breach or misuse of this sensitive information can severely erode patient trust and lead to legal repercussions.
When handled responsibly and ethically, this wealth of RWD generated by DTx offers unprecedented opportunities for generating RWE, enabling continuous assessment of product effectiveness, safety, and value in real-world settings. Balancing the need for data collection and robust privacy protections is a constant challenge.

A multifaceted approach is needed to address these challenges. By leveraging the unique strengths of DTx while proactively addressing their limitations, we can unlock their full potential to improve patient outcomes and transform healthcare delivery. As the field matures, continued collaboration between stakeholders will be critical to realising the promise of digital therapeutics.

Regulatory Hurdle
DTx require a fit-for-purpose evaluation and approval framework. This change requires the re-evaluation of classic trial design, such as placebos. Could a sham app replicate the user behavior and potential effects of the true intervention on a mobile device? Regulatory bodies will need to establish novel guidelines to define a sound placebo for a given indication in a DTx trial that still validly demonstrates whether or not a DTx works[8]. The concept of a generic drug, a copy with the same active ingredient, may not translate to DTx easily. The software, algorithms, as well as user interface are all involved in the therapeutic effect of a DTx program, which sets it apart from medications. Regulators will need to define the required similarity between a generic DTx and the original, ensuring it meets equivalent standards of efficacy and user experience for approval.

Further complicating the picture is the evolving nature of DTx programs. Unlike static medications, DTx can dynamically evolve through software updates and artificial intelligence. This raises the issue of the frequency of regulatory review. The industry proposes a 'Phase IV in perpetuity' model, where continuous data collection and testing ensure that as the DTx program evolves, its safety and efficacy are consistently monitored[9]. This change from a one-time approval model to ongoing surveillance mirrors the changing capabilities of DTx technology.

The traditional drug approval process can be lengthy and expensive, which may slow down the pace of innovation in the DTx segment. Regulators are exploring innovative approaches like the FDA's Digital Health Software Precertification Program[10]. This pilot program focuses on providing developers with robust quality control systems, allowing for faster iterations and efficient product development within a regulated framework.

We recommend:
- Adapting your regulatory strategy
- Assuring you have the correct privacy and security measures
- Leveraging innovative (virtual) trial designs
- Promoting data literacy of users by providing comprehensive education and support for healthcare providers, patients and other stakeholders

REIMBURSEMENT STRATEGIES FOR DIGITAL THERAPEUTICS

Traditional reimbursement models, primarily designed for pharmaceutical drugs and medical devices, often struggle to accommodate the unique value proposition of DTx. This results in a fragmented landscape with varying coverage policies and payment mechanisms across different countries and healthcare systems[7, 11]. The German DiGA program, with its fast-track pathway and automatic reimbursement for listed DTx products, stands out as a notable exception. However, even within this progressive framework, there are ongoing discussions surrounding the cost-effectiveness and evidence requirements for reimbursement. The recent legislative changes, including the shift towards performance-based reimbursement from 2026 onwards, highlight the ongoing efforts to refine and optimise DTx reimbursement models.

Emerging Reimbursement Models
As the DTx market matures, several reimbursement models are emerging, each with its own advantages and challenges:

1 Fee-for-service
This traditional model involves payment for each individual DTx intervention or service provided. While straightforward, it may not fully capture the long-term value and benefits of DTx.

2 Outcome-based or pay-for-performance
Reimbursement is tied to achieving specific clinical or patient-reported outcomes. This aligns incentives with patient benefits but can be challenging to implement due to the complexity of measuring and attributing outcomes to DTx interventions.

3 Subscription-based
Patients or payers pay a recurring fee for access to the DTx product. This can provide a predictable revenue stream for developers but may raise concerns about affordability and access.

4 Value-based
Focus on the overall value that DTx brings to the healthcare system, considering improved patient outcomes, reduced healthcare utilisation, and cost savings. While promising, it requires sophisticated data collection and analysis to demonstrate the full value proposition of DTx

The DTx reimbursement landscape is still in its early stages, but rapidly evolving. As the evidence base for DTx grows and innovative reimbursement models emerge, the potential for these digital solutions to transform healthcare and improve patient outcomes is immense. By addressing the challenges and opportunities outlined above, DTx developers, payers, and policymakers can collaborate to create a sustainable and equitable reimbursement system that supports the widespread adoption of these innovative solutions.

STRIKING THE RIGHT BALANCE FOR DTX DESIGN

Optimal DTx design lies at the intersection of innovation and practicality[12]. While pushing technological boundaries can lead to groundbreaking solutions, a thoughtful consideration of cost-benefit and user needs is essential. Indeed, creating a seamless user experience through intuitive interfaces and minimal friction is essential for user engagement.

However, it's worth considering whether developing entirely new apps or interfaces is always necessary. In some cases, leveraging existing communication channels, like text reminders or web-based platforms, might offer a more cost-effective and accessible solution, especially for populations with limited digital literacy or access to advanced technologies.

By prioritising user-centric design, evidence-based interventions, and responsible data practices, you can develop DTx solutions that are not only innovative but also sustainable, accessible, and truly impactful in improving patient outcomes. The debate between cutting-edge technology and practical implementation will continue, but the ultimate goal remains the same: to create digital therapeutics that are effective, affordable, and seamlessly integrated into the fabric of healthcare.

FUTURE PROJECTION

Digital therapeutics represent a transformative shift in the healthcare landscape, offering innovative solutions to some of the most pressing health challenges. The future of DTx lies in pushing boundaries and exploring novel approaches to treatment delivery. As technology continues to advance, the potential for DTx to improve patient outcomes, enhance treatment personalisation, and reduce healthcare costs becomes increasingly evident. Integrating

emerging technologies such as virtual reality, augmented reality, and wearable sensors can create immersive and interactive therapeutic experiences that enhance engagement and improve outcomes.

Developing DTx for underserved populations and addressing health disparities through equitable access and culturally sensitive design is another critical area for innovation. However, the successful integration of digital therapeutics into mainstream healthcare requires careful consideration of both their benefits and challenges. As Arcondis, we help guide the development and implementation of effective digital therapeutics, ultimately contributing to a healthier, more connected world.

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Tim, Ting-Yi Lin serves as the medical product lead at Arcondis. In this role, he helps clients shape medical products, design studies, identify risks, navigate market entry, and achieve product success. He is a physician-scientist with an MD-PhD specialising in neuro-ophthalmology. and co-founder of a medical diagnostics company.

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