



A DOSE OF **DIGITAL**

Can Pharma Make DTx a Healthy Business?

Francine Fram, Svetlana Gogolina

The Transformative Role of DTx: Pharma's Proposition

The healthcare landscape is undergoing a significant transformation. Digital therapeutics (DTx) are emerging as a potential driving force for change. Pharmaceutical companies are taking notice, recognizing the potential of DTx to improve patient outcomes, differentiate products, and generate real-world data on treatments. As a result, these digital solutions are increasingly becoming an

integral part of their business strategies. Although DTx pioneers have underscored the positive impact of these highly innovative tools, recent challenges faced by several prominent DTx companies highlight the need for a strategic and sustainable approach to navigate this complex and rapidly evolving market.

Digital Therapeutics (DTx) are evidence-based medical interventions which employ software programs to prevent, manage, or treat a variety of health conditions. DTx are increasingly being used to supplement traditional therapies by providing care and support to patients outside of the clinical setting, and by offering a highly personalized approach to treatment.



Navigating the Hurdles: Regulatory and Adoption Challenges

The rapid growth of the DTx sector has outpaced the ability of healthcare systems to adapt. Regulatory pathways are unclear and fragmented, leading to confusion and delays in obtaining market authorization and reimbursement. While a handful of countries, such as Germany, France and Belgium, have established fast-track pathways for DTx, these efforts are individual and lack harmonization. This regulatory uncertainty poses a significant obstacle to DTx development and adoption that is likely to persist for some time. Given that DTx employs advanced technologies such as generative AI, which can adapt in real-time, predicting their progression is a complex task. Consequently, regulators might find that post-market performance monitoring and surveillance present more of a challenge than the initial process of market authorization and reimbursement [1,2,3].

Despite predictions of widespread adoption once regulatory and reimbursement hurdles are overcome, experience has shown a need for caution. In Germany, where DTx have been

available by prescription since October 2020, adoption rates have been much lower than expected, and other countries with fast-track pathways have seen similar trends. The primary reason for this slow uptake is distrust from HCPs. Clinicians cite a lack of information, insufficient medical evidence, and incompatibility with traditional treatments as their reasons for not incorporating DTx into their practices. While generational differences contribute, this skepticism is also driven by DTx companies placing greater emphasis on technology than health economics and alignment with care continuity [4,5].

Given the high degree of innovation required in DTx development, it's understandable that many DTx companies focus on the singularity of their products. However, this strategy hasn't been well-received by clinicians and has diverted DTx creators from the crucial goal of gaining HCP trust. This can only be accomplished through the creation of products that meet the needs of both patients and clinicians, offer financial value, and seamlessly fit into care pathways. [6].



Insights from Digital Health: Commonalities with Patient Support Programs

Considering their unique characteristics, it's not surprising that DTx are encountering issues related to regulation, reimbursement, and adoption. While the evolution of the sector will provide valuable learnings, insights can also be gained by examining similarities with digital Patient Support Systems (PSPs).

Originally developed to improve patient adherence, PSPs have evolved into highly personalized tools that foster patient self-management and engagement while complementing traditional healthcare interventions. Similar to DTx, PSPs aim to enhance patient outcomes and optimize healthcare provider resources. Other attributes common to DTx and PSPs are their patient-oriented approach, application of behavior-oriented strategies, and capability to address gaps not filled by conventional healthcare services [7,8].

The success of PSPs hinges on their ability to integrate seamlessly into routine healthcare practices while offering tangible benefits to all stakeholders – patients, HCPs, and payers. These elements are equally vital for the success of DTx. For DTx companies to succeed, they need to address not only unmet clinical needs but also the unmet needs of the healthcare system. This does not mean that DTx companies should shift their focus from patients' clinical needs, as these remain fundamental to the value proposition of DTx. However, if the needs of the healthcare system are not considered, the chances of achieving widespread reimbursement and adoption significantly diminish.

One Key Lesson from the Early Days of DTx – Listening to the Customer

Understanding and responding to the needs of the healthcare system requires more than a profound understanding of the disease state and treatment protocols. It demands a comprehensive grasp of the patient journey, which includes emotional, social, and logistical elements, the challenges encountered by HCPs when managing conditions, and the evidence needed by payers for reimbursement.

“Voice of the Customer” research is crucial for gaining this understanding. Through in-depth stakeholder research, pharmaceutical companies can identify and prioritize requirements, uncover inefficiencies within the healthcare infrastructure, and assess the fit of potential DTx within the continuum of care. Additionally, this research can shed light on factors influencing healthcare decisions, project potential demand, and identify barriers to adoption.

This research can take various forms, such as patient interviews, analysis of social media discussions, physician surveys, and payer consultations. These techniques offer a holistic view of both the market landscape and stakeholder expectations. This critical information can then steer product development, ensuring that DTx solutions align with the needs and expectations of all stakeholders, thereby leading to improved access and uptake.



Building a Solid Foundation for Success

Building a successful DTx business necessitates a systematic, data-driven approach encompassing multiple stages, where each stage considers both the unmet clinical needs of patients and the broader requirements of the healthcare system. Leveraging Ipsos' experience, we propose a five-stage framework as a fundamental component for developing a resilient and scalable business.

Ipsos' 5-stage Framework for DTx Success

Phase 5

Promotes DTx literacy and clinical uptake

Phase 4

Optimizes user experiences & interoperability, fostering adherence and efficacy

Phase 3

Demonstrates efficacy and safety while reducing costs and benefiting workflow

Phase 2

Articulates benefits within the context of the broader healthcare system

Phase 1

Establishes the groundwork for product development



Phase 1

Market Understanding & Customer Priorities

lays the foundation for guiding product development decisions. This includes mapping the patient journey, identifying unmet needs and analyzing the competitive landscape.

Phase 2

Value Proposition Development draws on the insights from Phase 1 to ensure positioning resonates with all stakeholders, emphasizing not just clinical outcomes but also cost savings and workflow enhancements.

Phase 3

Efficacy, Safety and Health Economics Requirements

determine the design specifications, as prioritized by the value proposition, linking innovation with commercial feasibility.

Phase 4

Patient Engagement & Interoperability

are core features of successful DTx offerings, which are shaped by the value proposition and regulatory requirements.

Phase 5

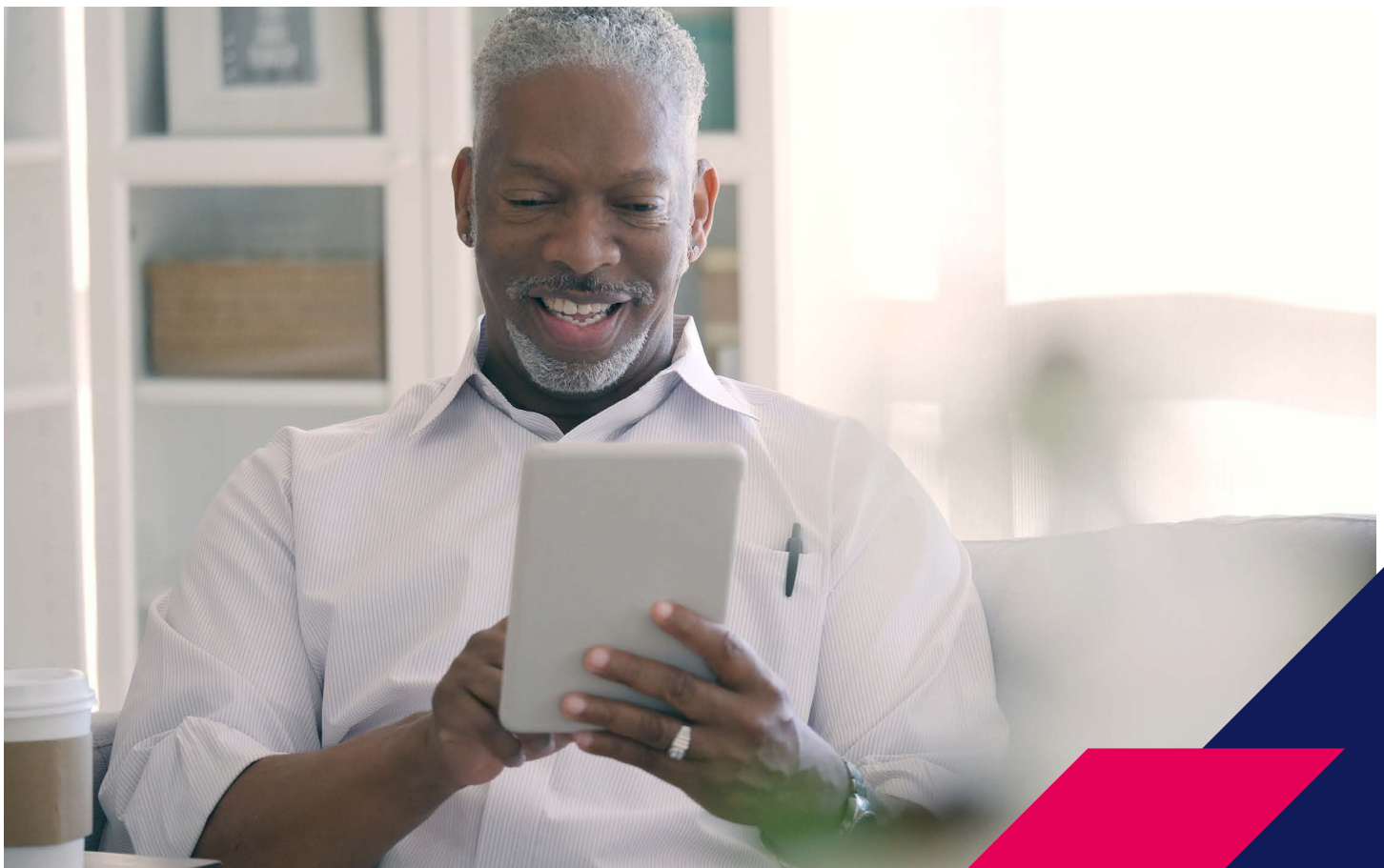
Market Shaping uses results from previous phases to determine how to best educate clinicians on the functionality, safety, and efficacy of DTx, enabling HCPs to clearly understand how DTx can complement and enhance their practices.

The strength of this framework lies in its iterative process where each stage feeds into the next, creating a unified and complementary development process suitable for various health conditions and stakeholders. While this may seemingly decelerate the pace of development, it has proven to be more efficient and economical than attempting to navigate the system through post-launch product adjustments. By investing in a detailed understanding of the market landscape, treatment pathways, and the comprehensive needs of the healthcare ecosystem, pharmaceutical companies can maximize DTx adoption and adherence, thereby building a sustainable business that benefits patients, garners HCPs trust, and provides value-based healthcare.

DTx: Beyond the Pill and Towards a Brighter Future

DTx solutions have the potential to revolutionize healthcare, offering a “beyond-the-pill” approach to disease management and patient empowerment. However, achieving widespread adoption requires a strategic approach that prioritizes market understanding, addressing stakeholder needs and fostering collaborations within the larger healthcare system.

By building a solid foundation based on critical insights that support evidence-based decision making, pharma companies can pave the way for a future where DTx plays a central role in improving patient outcomes, enhancing healthcare delivery, and transforming the healthcare landscape for the better.



References

1. Wang, C., Lee, C. & Shin, H. Digital therapeutics from bench to bedside. *npj Digit. Med.* 6, 38 (2023). <https://doi.org/10.1038/s41746-023-00777-z>. <https://www.nature.com/articles/s41746-023-00777-z>
2. Van Kessel R, Srivastava D, Kyriopoulos I, Monti G, Novillo-Ortiz D, Milman R, Zhang-Czabanowski WW, Nasi G, Stern AD, Wharton G, Mossialos E. Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping. *JMIR Mhealth Uhealth.* 2023 Sep 29;11:e49003. doi: 10.2196/49003. PMID: 37773610; PMCID: PMC10576236. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10576236/>
3. EFPIA 'Improving access to digital therapeutics in Europe' June 2023, [improving-access-to-digital-therapeutics-in-europe.pdf](https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-in-europe.pdf) (efpia.eu) <https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-in-europe.pdf>. Accessed 5 March 2024.
4. Dittrich F, Mielitz A, Pustozerov E, Lawin D, von Jan U, Albrecht UV. Digital health applications from a government-regulated directory of reimbursable health apps in Germany—a systematic review for evidence and bias. *Mhealth.* 2023 Jul 24;9:35. doi: 10.21037/mhealth-23-17. PMID: 38023782; PMCID: PMC10643174. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10643174/>
5. Groene N, Schneck L. Covering digital health applications in the public insurance system: how to foster innovation in patient care while mitigating financial risks—evidence from Germany. *Front Digit Health.* 2023 Oct 11;5:1217479. doi: 10.3389/fdgth.2023.1217479. PMID: 37886669; PMCID: PMC10598733. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10598733/>
6. Rassi-Cruz M, Valente F, Caniza MV. Digital therapeutics and the need for regulation: how to develop products that are innovative, patient-centric and safe. *Diabetol Metab Syndr.* 2022 Apr 1;14(1):48. doi: 10.1186/s13098-022-00818-9. PMID: 35365189; PMCID: PMC8972652. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8972652/>
7. Palfy E, Lewis DJ. Real-World evidence revelations: The potential of patient support programmes to provide data on medication usage. *PLoS One.* 2024 Feb 8;19(2):e0295226. doi: 10.1371/journal.pone.0295226. PMID: 38330001; PMCID: PMC10852303. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10852303/#:~:text=In%20the%20past%2020%20years,stay%20close%20to%20their%20customers.>
8. a:care "Patient Support Programs: personalized digital adherence support" <https://acarepro.abbott.com/articles/gastroenterology/patient-support-programs-personalized-digital-adherence-support/>. Accessed 2 May 2024