Realizing the potential value of digital therapeutics

An ecosystem-driven approach to designing your go-to-market strategy

EY

Building a better working world

Digital health has evolved, from isolated remote monitoring technologies for cardiac and diabetic patients 10 years ago to ubiquitous fitness devices and wellness apps today.

This evolution is creating new business model opportunities and operating model challenges for global health care and life sciences organizations.

The next wave of digital health is upon us: digital therapeutics (DTx) is an emerging subset of evidence-based, clinically evaluated software products and services. Maximizing the clinical, financial and operational value of these new offerings requires biopharma, medtech and other health care stakeholders to rethink DTx as an entirely new platform-based business model and ecosystem to deliver outcomes and drive stakeholder awareness, adoption, engagement and growth.

Projected to reach $5.7b in 2025,[1] the global DTx market holds the promise of successfully delivering on the Institute for Healthcare Improvement's Triple Aim: improved access to better quality care at a lower cost. Globally, payers and policymakers are gaining confidence in the clinical impact of DTx solutions and beginning to define tailored DTx reimbursement policies. In the US market, DTx solutions are gaining momentum due to streamlined regulatory approvals (i.e., U.S. Food and Drug Administration's Software Precertification Pilot Program)[2] and digital formularies established in 2020 by two of the "big three" pharmacy benefit managers (PBMs) in 2020 that certify clinical efficacy and outcomes, simplify pricing models and contracting, and facilitate reimbursement for DTx solutions.[3]

In order for DTx solutions to be covered and paid for within traditional reimbursement models, organizations launching these DTx solutions will require an evidence-based approach to demonstrate clinical, economic and "quality of life" value. Increasingly, the value of these solutions will be proven by real-world evidence (RWE), efficiencies and outcomes improvements across the end-to-end, cross-constituent experience. It will be critical for organizations pursuing DTx solutions to take a broad-based, customer-focused view of their value proposition for various stakeholders versus following a more traditional, product-focused approach.

The challenges for many organizations that have entered the DTx market are stakeholder awareness, adoption and engagement. To date, most DTx solutions have entered the market with narrowly defined, product-centric business models and go-to-market strategies. Their focus has been on selling more product rather than solving unmet (and unarticulated) needs of patients and other critical stakeholders across the end-to-end continuum of care. The result is a fragmented, confusing, overcrowded marketplace of isolated digital point solutions. There is no truly integrated, patient-centric experience to help navigate our complex health care system.

To realize the full potential of DTx, health care and life sciences organizations must redefine their business models and rethink their ecosystem of stakeholders that directly and indirectly affect the success of their go-to-market strategies.

1 "Global Digital Therapeutics Market (2020-2025) By Application, Product and Sales Channel and Geography and the Impact of Covid-19 with Ansoff Analysis," *Research and Markets website*, https://www.researchandmarkets.com/reports/5137778/global-digital-therapeutics-market-2020-2025-by#pos-0, accessed on 11 January 2021.

2 "Digital Health Software Precertification (Pre-Cert) Program," *FDA website*, https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program, accessed on 11 January 2021.

3 "Evernorth Digital Health Formulary," *Express Scripts website*, https://my.express-scripts.com/digital-health-formulary.html, accessed on 4 January 2021. "Point Solutions Management," *CVS Health website*, https://payorsolutions.cvshealth.com/point-solutions-management, accessed on 4 January 2021.

Unpacking the digital health market landscape and business models

Digital health encompasses a wide range of health care technologies and solutions that address a variety of needs, conditions and use-case applications. While there are many ways to segment this market, we view it on a spectrum of business models and ecosystem complexity across six broad capability focus areas. We have outlined this complexity spectrum in Figure 1:

Figure 1:

Degree of business model and ecosystem complexity

Education and search	Engagement and community	Well-being and fitness	Navigation and advocacy	Telehealth and remote monitoring	Digital therapeutics (DTx)
Offers patient education resources and tools for provider and medication research	Develops health educational content and drives engagement and adherence to treatment	Helps patients build and sustain healthy behaviors	Offers health care concierge services to resolve clinical, administrative and benefits-based issues	Delivers direct-to-consumer virtual care services	Diagnoses, treats and mitigates diseases through evidence-based digital interventions and care management
Illustrative offerings					
GoodRx	**AbbVie Care**	**Headspace**	**Accolade**	**MDLive**	**Pear Therapeutics**
WebMD	**PatientsLikeMe**	**Hinge Health**	**Quantum Health**	**Teladoc**	**Click Therapeutics**
ZocDoc	**GetWellNetwork**	**Apple Fitness**	**Journi**	**VivifyHealth**	**Propeller Health**

As shown in Figure 1, the digital health landscape spans from "education and search" tools, like GoodRx and ZocDoc, that address the basic health care information-based needs of consumers to "well-being and fitness" apps and "telehealth and remote monitoring" offerings. On the far end of the spectrum, we see DTx solutions emerging to provide more expansive, clinically proven solutions for targeted conditions and therapy areas.

These DTx solutions are the next evolution on the digital health continuum to improve care coordination. In this category are companies like Click Therapeutics, which recently partnered with Boehringer Ingelheim to develop and commercialize CT-155, a prescription digital therapeutic to aid in the treatment of schizophrenia.[4] Another example is Propeller Health, which provides a sensor that attaches to medication inhalers and tracks data through an integrated mobile app for patients with asthma or COPD.[5] Voluntis is pursuing an business model to provide branded and "white-label" DTx development and commercialization solutions with biopharma and medtech companies.[6] Across these alternative DTx approaches, the necessary clinical focus requires new levels of ecosystem-based thinking. Unlike other digital health solutions, these DTx offerings require US FDA or similar regulatory agency approval in other countries based on clinical trials to demonstrate safety and efficacy. As a result, this increased investment of time and capital in product development creates more business risk and significantly higher pressure on the marketing and commercial sales teams to accelerate successful go-to-market strategies for DTx launch, scale-up and growth.

Many organizations pursuing DTx solutions, from digital health startups to biopharma companies, have struggled to gain awareness, adoption and engagement following launch due to their narrow focus on a small group of stakeholders. In fact, the nature of DTx business models tends to require a deeper focus on specific clinical conditions to gain regulatory approval. However, delivering a compelling end-to-end user experience and end-user adoption requires a more systematic understanding of the value exchanges with a broader ecosystem of stakeholders. It is this broader DTx ecosystem that impacts product-market fit and improves the desirability, feasibility and viability of the DTx solution. Many organizations fail to consider unmet needs of stakeholders across this broader DTx ecosystem and fail to conduct early in-market experimentation to validate and refine critical business model assumptions prior to launch.

More importantly, however, the go-to-market strategy for these DTx solutions needs to consider a broader set of ecosystem stakeholders for successful market entry. If it does not, these DTx solutions launch into a sea of digital health alternatives targeting the same stakeholders with a similar value proposition. Without a strategic rudder to guide market entry, DTx solutions lose valuable time and unnecessarily burn cash attempting to build awareness and differentiate their solution. In many ways, defining a robust go-to-market strategy is just as important as product development and clinical trials for DTx business model success.

4 "Click Therapeutics – Products & Pipeline," *Click Therapeutics website*, https://www.clicktherapeutics.com/products, accessed on 4 January 2021.

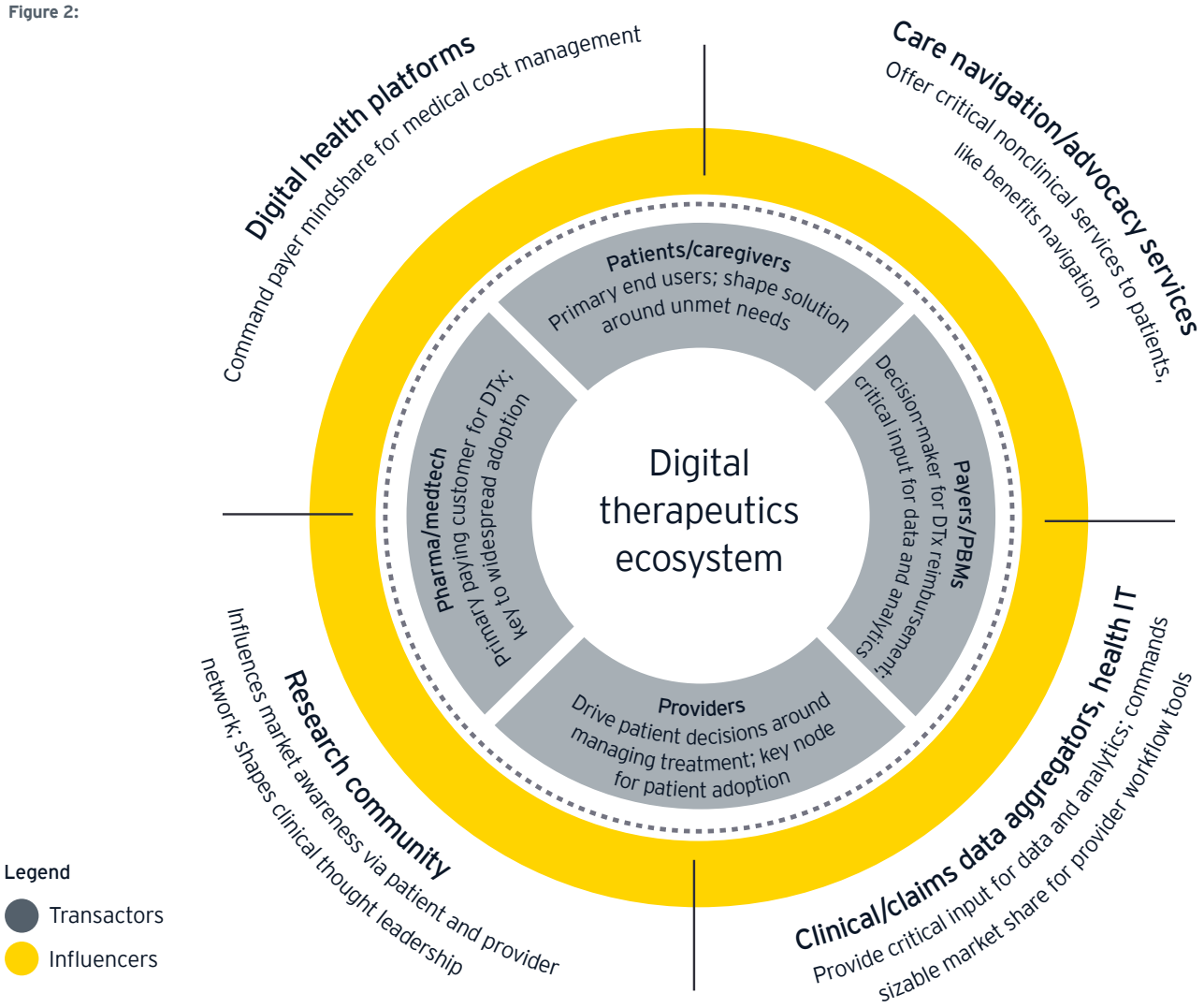
5 "Propeller Health – Solution," *Propeller Health website*, https://www.propellerhealth.com/the-propeller-solution, accessed on 11 January 2021.

6 "Insulia," *Insulia website*, https://insulia.com/, accessed on 11 January 2021.
"Voluntis announces its new strategic roadmap," *Voluntis website*, https://voluntis.com/en/news/news-1/2020/voluntis-announces-its-new-strategic-roadmap, accessed on 11 January 2021.

Defining your digital therapeutics ecosystem and critical stakeholders

Understanding the broader stakeholder ecosystem surrounding your DTx solution and adapting the value proposition to high-priority stakeholders is a critical success factor to accelerating go-to-market awareness, adoption and engagement for DTx solutions. In defining their DTx ecosystems, most organizations tend to focus on the inner gray ring in Figure 2, stakeholders that are considered direct "transactors" with the solution. These transactors form the core of the DTx ecosystem, providing products and services, information and emotional value exchanges that improve clinical outcomes. To accelerate DTx market entry and growth, however, the stakeholders in the outer yellow ring are critically important. These indirect "influencers" can accelerate and enable the success of DTx awareness, adoption and engagement that is critical to demonstrating improved patient outcomes. Many organizations fail to adequately consider this broader ecosystem of transactors and influencers in defining their DTx value propositions and go-to-market strategies.

Figure 2:



Once a more robust stakeholder ecosystem is developed, organizations launching DTx solutions must adapt their value propositions and positioning to reflect the "give-to-get" relationship and value exchanges with these ecosystem transactors and influencers. As detailed in Figures 3 and 4, accelerating go-to-market awareness, adoption and engagement requires thinking through the value the DTx solution "gives to" and "gets from" high-priority ecosystem stakeholders.

Figure 3:

DTx solution "give-to-get" value exchanges with ecosystem "transactors"

"Transactor" stakeholder group	"Give" — value to stakeholder group	"Get" — value from stakeholder group
Patients/caregivers	▸ Personalized, on-demand assistance to manage condition, risk factors and co-morbidities ▸ Improved access to trusted information and quality of life	▸ Insights on challenges with managing therapy area and RWE dataset ▸ Improved adherence to drug/device/behavior plan
Payers/PBMs	▸ Lower care management costs and resource utilization (medical cost management adherence to treatment) ▸ Improved clinical outcomes, overall health and wellness	▸ Access to large population and disease management programs to drive awareness and adoption ▸ Inclusion on formulary and reimbursement payments
Providers	▸ More effective patient-provider communication and 360° view of patient history and trends ▸ Actionable decision support to improve outcomes	▸ Identification of targeted patients for DTx platform ▸ Improved patient awareness, adoption and trust
Pharma/medtech	▸ RWE, demonstrated outcomes, and insights on "patient experience" to inform solution and future product road map ▸ Direct patient engagement for clinical trial recruitment	▸ Co-developed solutions, co-funding and investment ▸ Access to resources to build awareness and scale

Figure 4:

DTx solution "give-to-get" value exchanges with ecosystem "influencers"

"Influencer" stakeholder group	"Give" — value to stakeholder group	"Get" — Value from Stakeholder Group
Digital health platforms	‣ Increased depth of clinical information, data analysis, and insights on targeted therapy areas and conditions ‣ Improved patient outcomes and platform value proposition ‣ Accelerated expansion to new markets/therapy areas	‣ Improved patient access, awareness, adoption and engagement to encourage behavior change ‣ Expanded patient experience, data, and insights into co-morbidities and behaviors
Care navigation/ advocacy services	‣ Improved access to more targeted, clinically oriented solutions and information to address patient needs ‣ Improved patient outcomes and platform value proposition	‣ Improved patient awareness, adoption and engagement with DTx solution ‣ Increased consumer/constituent support and access to a more comprehensive solution experience
Clinical/claims data aggregators and other health IT	‣ Licensing fees and potential source of revenue ‣ Expanded data and insights into patient co-morbidities, claims and behaviors that drive outcomes	‣ Aggregated, de-identified clinical and claims data ‣ APIs to embed DTx solution into clinical workflows and real-time information capture
Research community	‣ Aggregated, de-identified clinical and behavioral data ‣ Patient education partner and content provider	‣ Brand credibility with medical community to generate awareness and acceptance ‣ Access to clinical specialists, research grants and/or principal investigators to design/conduct clinical trials

Thinking through these give-to-get value exchanges for high-priority stakeholders is a critical success factor for designing successful DTx go-to-market strategies. Although Figures 3 and 4 provide initial guidelines, each DTx solution will have its own unique perspectives on high-priority ecosystem stakeholders and give-to-get value exchanges. Additionally, identifying and prioritizing the specific partners and organizations across these ecosystem stakeholder groups helps define targeted value propositions and give-to-get relationships.

Where to go from here

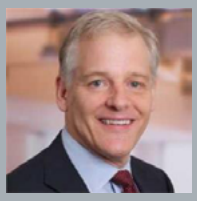
DTx solutions are the next evolution of digital health. Beyond developing compelling user experiences, organizations launching DTx solutions must rethink their stakeholder ecosystems and value exchanges to define a successful go-to-market strategy to accelerate market entry. For executives leading these organizations, there are five strategic questions to address:

1. Who are the high-priority stakeholders in your DTx ecosystem? Can you identify specific entities and/or organizations that have an interest in your DTx solution?
2. What value will your DTx solution provide to these ecosystem stakeholders? What are the "jobs to be done," and how do stakeholders complete these tasks today?
3. What value will your organization or DTx solution receive in return from these stakeholders? How critical are these value exchanges to the long-term success of your DTx solution?
4. How and when will you pursue relationships with targeted ecosystem stakeholders? How will you update your sales messaging to quantify the impact of value exchanges?
5. What is your overall strategic roadmap and timeline for the go-to-market strategy? How do you make certain that this go-to-market strategy aligns with your product development and release schedule? Access related article describing the *Strategic Roadmap* at ey.com.

Concluding thoughts

An ecosystem approach can help organizations realize the potential value of digital therapeutics. By increasing the focus on clearly articulated "give-to-get" value exchanges with high-priority stakeholders, an ecosystem-driven approach can accelerate the design of successful DTx go-to-market strategies. For organizations launching DTx solutions into the increasingly crowded digital health market, this ecosystem approach will help improve DTx solution awareness, increase adoption, encourage engagement and deliver growth.

To learn more, contact the
EY Global Health Sciences and Wellness Strategy and Digital Innovation Team:



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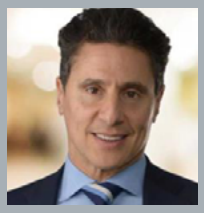

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