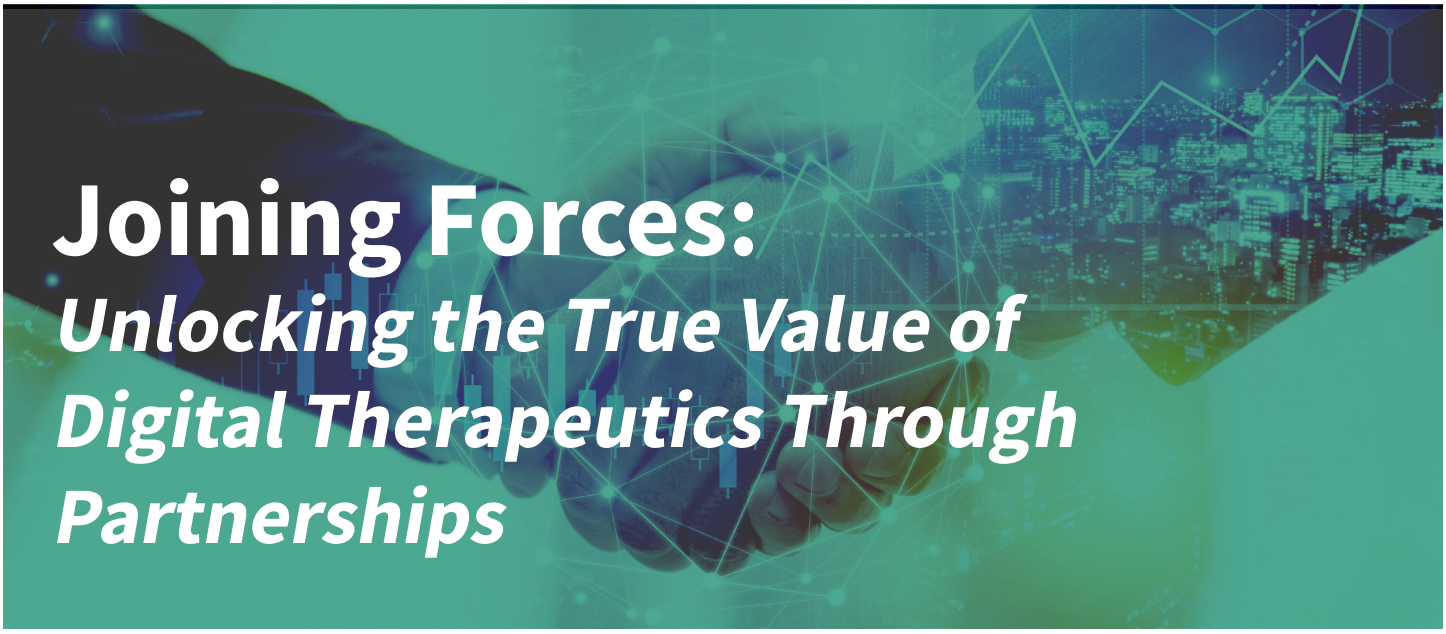
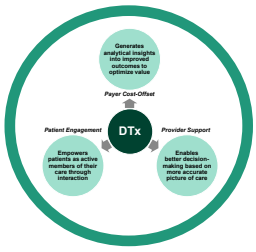


Joining Forces:
Unlocking the True Value of Digital Therapeutics Through Partnerships

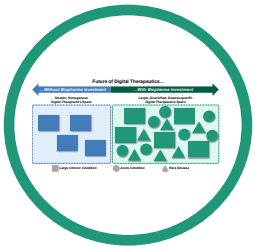
Digital therapeutics are on the rise, and biopharma companies have the unique opportunity to translate their value to stakeholders through partnerships. In this white paper we explore the broad value potential of these technologies across biopharma portfolios and why near-term integration will help forward-looking companies gain a competitive edge. Learning from partnerships past and present, this paper will help players proactively plan around key challenges for integration and harness the full potential of digital therapeutics.

THE BRIEF



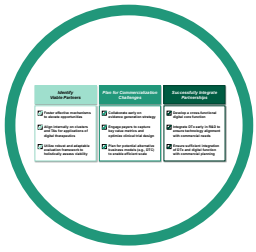
Understanding Breadth of DTx Value

Outlining use cases of digital therapeutics for key stakeholders and portfolios



Investing Early to Establish Leadership

Clarifying key incentives for near-term investment in digital therapeutics



Proactively Plan for Partnership Success

Establishing a roadmap for b iopharma to overcome key challenges

Introduction

The digital health industry is experiencing an era of unprecedented growth, prompting biopharmaceutical companies to consider how an increasingly complex array of digital tools can be most effectively leveraged to enhance patient outcomes and provide value to stakeholders. Digital therapeutics – tools that directly engage with patients to influence behavior or outcomes – are a key class of emerging technologies with the potential to augment the role of biopharmaceuticals in creating value through the data and engagement they provide. While digital health technologies are experiencing substantial interest and investment (~$5 B in H1 2020), digital therapeutic developers and biopharma companies have struggled to establish mutually productive partnerships that enable the realization of their combined value potential.

A wide range of hurdles, from regulatory to commercial, need to be overcome to realize the potential of digital therapeutics. As biopharma companies encounter these challenges through partnerships, a perception often develops that digital therapeutics may not strategically fit within their portfolios or that more clear demonstrations of added value are needed to drive investment. In addition to hindering the value that can be created by digital therapeutics, these perceptions can limit their integration into strategic planning for key functions, creating roadblocks to successful execution and partnership. Reframing the expected role for digital therapeutics and proactively planning to deeply integrate these tools as part of digital transformation efforts can help biopharmaceutical companies to enhance their future competitiveness in the emerging digital age.

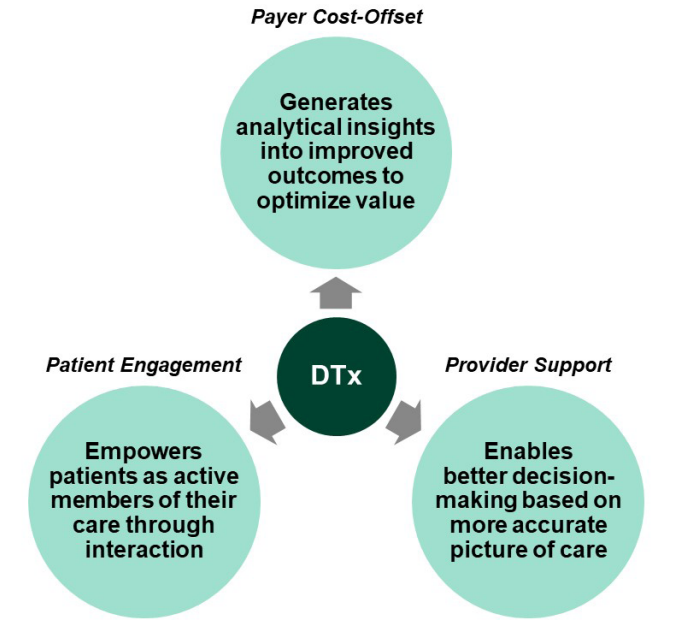
We interviewed 20 biopharma digital executives, digital therapeutics developers, and payers to delve into the dynamics that drive successful partnerships between biopharma companies and digital therapeutics companies. This paper is designed to help biopharma stakeholders: 1) Align on the value that can be achieved through digital therapeutic partnerships, 2) Clarify when to invest their energies, and 3) Establish a tactical roadmap to developing partnerships that ensures success and value translation.

The Role and Value of Digital Therapeutics

The potential of digitalization in a competitive global market has not been lost on biopharma, as shown by the breadth of companies exploring digital ventures, developing digital-focused functional teams, or engaging in digital transformation of their operations. Sanofi and AstraZeneca, for example, have both established numerous collaborations with digital health innovators (e.g., Eko, US2.ai); Takeda has also committed to transitioning the large majority of its business and R&D operations to cloud-based platforms, with the vision of establishing a robust digital architecture that can flexibly incorporate novel technologies, an approach that will enhance its competitive edge. Investments are widespread and create opportunity to optimize digital therapeutic value.

Digital therapeutics offer biopharma companies opportunities to enhance their competitiveness and value to key stakeholders by optimizing and tracking outcomes for payers, engaging with patients to improve quality of experience, and supporting providers with additional metrics of patient performance. Integration of digital therapeutics into biopharma digital architectures can facilitate new insight generation and streamline the process for adapting these technologies to new indications across a therapeutic area and the broader portfolio.

FIGURE 1 - Digital Therapeutic Value Propositions for Key Stakeholders



Payers

The novel data generation capabilities of digital therapeutics (e.g., pill compliance, quality-of-life measurements and other PROs) have the potential to provide meaningful analytical insights to optimize payer value for companion treatments. Payers are

interested in reimbursing digital therapeutics proven to improve outcomes, as exemplified by the broad coverage of Teva's FDA-approved ProAir Dighaler, a smart inhaler used in combination with inhaled albuterol. Deeper implementation of digital therapeutics across a company's portfolio may also enable portfolio-level analyses that support favorable positioning in payer contracting, particularly if data can be seamlessly integrated into payer data architectures. In the future, such data tracking and portfolio-level insights may become vital to contracting with larger payer organizations.

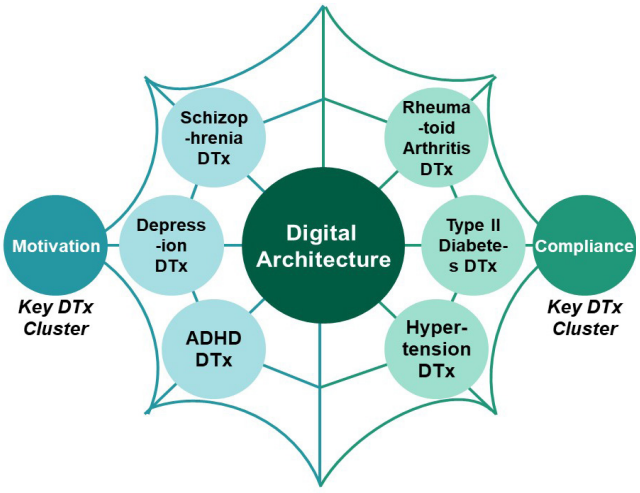
Patients

Digital therapeutics offer biopharma companies capabilities to empower patients to be more proactively involved in their care and increase the attractiveness of companion drugs. In spaces where patient reported outcomes are commonly tracked and burdensome (for example, Alzheimer's disease), digital therapeutics may significantly reduce this burden on patients and facilitate increasingly robust data collection. Whether a digital therapeutic provides direct therapeutic benefit (e.g., EndeavorRx), tracks patient reported outcomes, or grants patients access to their own tracked information, this engagement expands the perceived quality and breadth of services provided by a companion product and has the potential to motivate patient preference. In the future, companion digital therapeutics may be a key lever to establish patient awareness and excitement for pharmaceuticals in increasingly competitive disease areas.

Providers

Data from digital therapeutics can support providers in creating a more accurate portrait of therapeutic efficacy and patient quality of life. Development of insights around compliance and patient-reported outcomes and drug performance may establish differentiation in increasingly crowded disease areas and enable physicians to make the optimal treatment decision for patients. The recent partnership of Voluntis with Redox exemplifies how digital therapeutics can be conveniently deployed for providers by operating within existing clinical workflows. Companies that streamline the integration of data and insights into electronic health record systems can mitigate information overload, decrease hassle for providers, and optimize the added value of their digital therapeutic.

FIGURE 2 - An Example of Digital Therapeutics Integration to Address Key Problem Clusters Across Portfolios

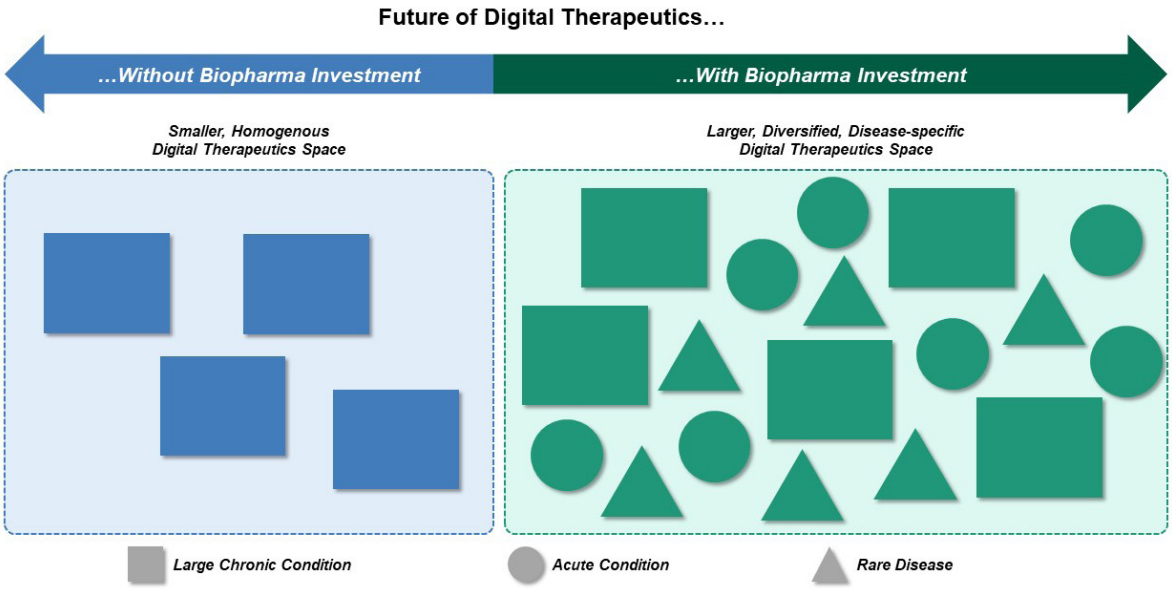


Investing in or collaborating with a digital therapeutic innovator can help a biopharma company optimize its digital transformation and assume its role as a digital intermediary of value for key stakeholders. Initial investments or collaborations can also support biopharma companies to expand the role of these tools, creating a template for success and the deployment of these technologies across their portfolios. Digital therapeutics can achieve this breadth of impact by addressing key clusters of problems common to multiple disease areas (e.g., compliance, tracking adverse events, patient motivation) driving synergies for deployment in new indications and the development of higher value products in the long term. AstraZeneca's AMAZE platform is a primary example of this, which is currently being deployed to tackle key challenges for chronic disease management across a variety of disease areas (e.g., asthma, heart failure) relevant to the company's portfolio. In this regard, partnering with or investing in innovators focused on digital therapeutics is a highly attractive value proposition for biopharma.

When to Invest in Digital Therapeutics

The decision of when to invest in digital therapeutics will have meaningful implications for the competitiveness of biopharma companies in a future landscape where digital therapeutics are widely integrated. Some are concluding that the current commercial state of digital therapeutics suggests that a watch-and-wait approach to investment

FIGURE 3 - Diversification of Digital Therapeutics Landscape with Biopharma Investment



and partnership is a reasonable path forward. Concerns around commercialization challenges, the maturity of digital therapeutics, their fit with pharma portfolios, and their ability to commercially scale may appear to support delaying involvement. Such hesitant organizations may anticipate future commoditization of data through the growth of expansive external digital therapeutics-focused entities that offer biopharma companies equal access to their platforms.

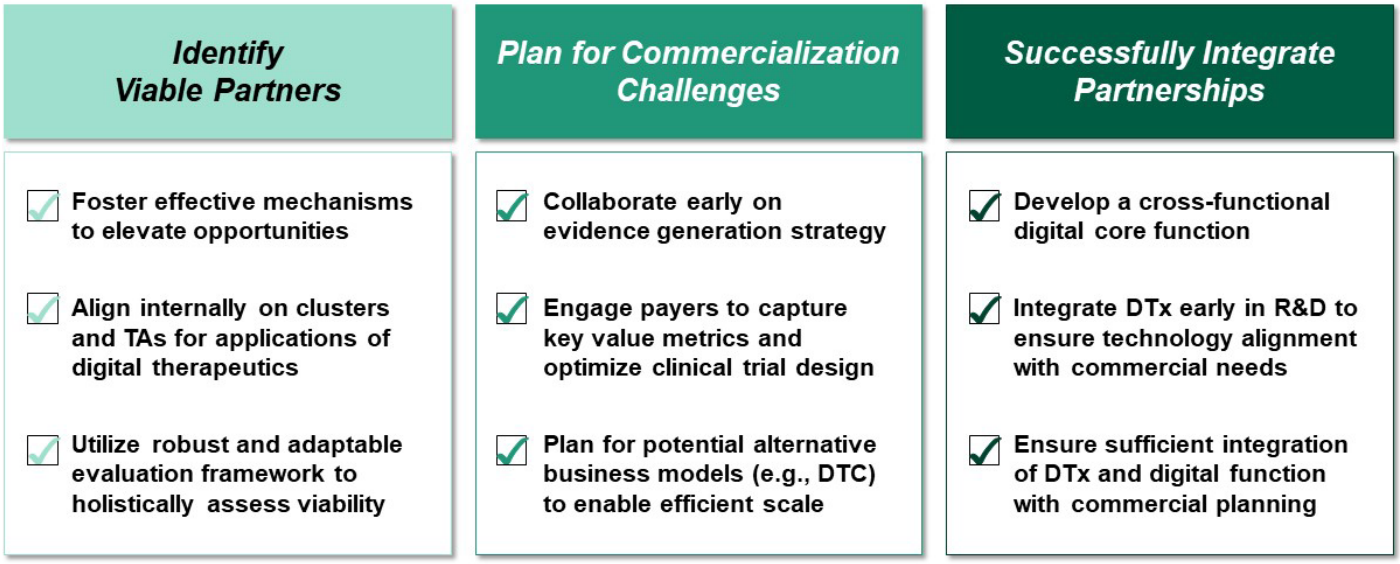
However, a future in which there is a commoditized market for digital therapeutics across a range of disease states is unlikely. Digital therapeutics require specialization to their respective disease state to improve patient outcomes, with some states benefiting tailored cognitive behavioral regimens to manage treatment compliance and others requiring directly validated therapeutic interventions (e.g., ADHD, amblyopia). Chronic disease states with broad populations and accessible biomarkers that directly tie to health outcomes (e.g., Type II Diabetes, obesity), have enabled organizations such as Livongo and Noom to achieve commercial scale. Conversely, rare or acute disease states have not benefited from these advantages and may struggle to scale and attract investment. Biopharma partnership may be crucial to unlocking the value of digital therapeutics for rare or acute disease states (e.g., Voluntis with BMS and AZ in oncology, Rehab+ with Amgen for heart attack prevention) that would otherwise struggle in a future market biased towards common, chronic conditions.

Given the nascent state of the digital therapeutics landscape, biopharma companies that understand the full value offered by digital therapeutics and invest early can establish a competitive advantage. Investing in or partnering with digital therapeutics in the near-term, particularly in rare or acute disease states, will enable companies to proactively shape the landscape from a position of leadership. These players will be able to optimize the outcomes of their products and attract patient interest in using a drug's accompanying digital therapeutic. Furthermore, near-term investment can help biopharma companies learn how to effectively integrate these products and build a template for successful implementation of digital tools across their portfolio of therapeutics. While prior partnerships between digital therapeutics developers and biopharma have been challenging to execute, these collaborations have established key learnings on how they can be implemented successfully and enable biopharma to effectively translate the value of digital therapeutics.

How to Effectively Translate Value

Given the historical challenges in this space, biopharma companies will need to reassess their approach to developing these partnerships to establish leadership. Identifying viable partners, proactively planning for commercial challenges, and successfully integrating partnerships have been key areas of difficulty that have hindered collaborations, suggesting that a thoughtful and refreshed approach to tacking these challenges may be necessary for partnership success.

FIGURE 4 - Core Considerations for Successful Translation of Digital Therapeutic Value



Identifying Viable Partners

The limited number of successful partnerships results from a lack of appropriate mechanisms to source digital therapeutics in smaller organizations, as well as misalignment between a more established biopharma company's perceived needs and the offerings from innovators. While digital innovation-focused groups exist within many large pharma companies, smaller organizations often lack dedicated individuals to proactively drive digital collaborations. Furthermore, when individuals at these companies identify attractive opportunities, mechanisms may not exist for elevating these opportunities to relevant decision-makers. Larger organizations have the capabilities to readily source partnerships, but the desire for a "one-size fits all" digital health technology vs. an adaptable digital therapeutic tailored to a specific disease state can lead to skepticism of the portfolio fit of these technologies. For example, a GI-focused digital therapeutic with a patient information tool, a social component, and related gamification might add value to the GI portfolio but the potential value of GI toxicity tracking for a blockbuster oncology agent might not be readily apparent through a more cursory evaluation. This mindset to evaluating digital therapeutics can limit the value that could be achieved through partnerships.

To overcome these barriers, organizations need to ensure they have a robust mechanism to elevate opportunities and a systematic evaluation framework that appreciates the breadth of value that could be obtained through partnerships. Smaller organizations should consider allocating business development time to considering digital therapeutic integration. Conversely, larger organizations should establish a clear framework for the value that can be achieved through digital therapeutics and foster a willingness to experiment. Dedicated digital innovation groups should adopt a proactive approach to sourcing tools relevant to portfolio disease areas and common problem clusters, establishing a framework that considers modalities that may have cross-therapeutic area applicability and benefit other indications. Implementation of these recommendations can ensure biopharma companies do not overlook potential collaborations of significant value to their portfolio.

Proactively Planning for Commercial Challenges

Biopharma companies that have appreciated the potential of digital therapeutics have often entered into partnerships with unintended consequences, ultimately discovering the commercial and access challenges these products face as they approach launch. These challenges stem from the limited regulatory framework currently in place, which creates limits payer understanding of the true value of technologies achieving FDA clearance. As such, the evidence package pursued by resource-strapped digital therapeutic innovators often does not achieve the standards required by payers at launch, leading to poor access and the need for extensive real-world evidence collection to bridge to sustained reimbursement. These access hurdles have required many digital therapeutic developers and their partners to commercialize direct-to-consumer or provide free access, often leading to misalignment with the preferred commercialization strategy of a biopharma partner. This was a key challenge for Otsuka during their partnership

with Proteus for Abilify Mycite, which failed to obtain widespread coverage given a lack of evidence showing an impact on compliance. The late realization of these challenges can lead to inadequate preparation for the evidence package necessary to support broad access and a lack of established expertise necessary to support continued partnership or direct-to-consumer commercialization.

When pursuing partnerships with digital therapeutics it is crucial to anticipate these challenges in advance and proactively plan for them as partnerships are sourced and integrated. It is critical to collaborate on the evidence generation strategy early to ensure a trial is appropriately scaled and supported by robust metrics to create a compelling value story. Biopharma partners should engage payers to clarify key metrics to include in trial designs to ensure a robust package is tailored to stakeholder needs. If value demonstration is anticipated to be challenging in a specific disease state, biopharma partners should enter partnerships understanding the potential for using a direct-to-consumer business model as a bridge and prepare the marketing infrastructure necessary to support the product commercially. Implementation of these strategies can establish a framework for successful commercial planning and ensure that biopharma companies enter partnerships ready to overcome key challenges.

Successfully Integrating Partnerships

Once collaborations are established, internal misalignment on a digital therapeutic's value for specific brands and limited integration within their business can create structural barriers to successful execution. Lack of a core digital function often leads to limited personnel dedicated to successful digital therapeutic integration as well as poor alignment on the strategy of these tools for a specific brand. This can lead to narrow perceptions of digital therapeutics as tools to opportunistically support select commercial initiatives (e.g., improved patient engagement), unanchored to organizational commitments to this product class. If digital functions exist within business units, siloing of these individuals from key commercial decision-makers can still lead to poor tactical integration and misalignment. Opportunistic incorporation of a digital therapeutic at mid-to-late stages of drug life cycle can exacerbate structural barriers, as tools are deprioritized amongst other commercial or LCM initiatives due to limited proactive planning and alignment with established goals. Current business unit structures and a lack of a core digital function will continue to hinder successful digital therapeutic partnerships without change.

Successful partnership execution requires dedicated digital functions, particularly at the brand level in large pharma organizations, and greater flexibility of business units and commercial teams to integrate these individuals and ensure alignment with strategic priorities. Additionally, biopharma companies need to be more proactive in planning for digital therapeutic integration early in the research and development process. This can enable the appropriate customization of tools to data generation needs established during clinical development and ensure promotional alignment with the partnered drug to create synergies for stakeholder receptivity to both products. Creating a versatile company-wide data architecture can also clarify the fit of digital therapeutic data streams within the organization's broader data strategy and allow tools to be streamlined early in the R&D process to integrate seamlessly. This can establish a template for how future tools can be adapted to this architecture in new disease areas and lay the foundation for an internal digital therapeutic development engine across a company's portfolio. Implementation of these strategies can create the structure for partnership success and enable companies to translate the value of digital therapeutics across their organization.

Conclusion

While challenges exist, digital therapeutics have substantial potential to complement and strengthen the value of pharmaceutical products and establish differentiation at the portfolio level for stakeholders. Biopharma players that proactively engage now to tackle these challenges and shape stakeholder priorities will gain a critical competitive edge, while those who wait may struggle to adapt their organizations to the future landscape. Furthermore, forward-looking organizations that adopt a robust framework to align on priorities for partner evaluation, proactively plan for commercial challenges, and modify their business unit structures to support greater digital integration will position themselves for partnership success.

Significant value remains to be unlocked from digital therapeutics, and biopharma companies have the opportunity to partner early and establish their future leadership by translating this value.

About ClearView Healthcare Partners

Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life science sector.

The firm combines international industry knowledge and deep scientific expertise across a range of therapeutic areas with an extensive network of external stakeholders to deliver practical and actionable recommendations to our clients' most complex challenges. The firm's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medtech and digital, and diagnostics companies worldwide.

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