Digital Therapeutics

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Executive Summary

Digital therapeutics are poised to change healthcare by allowing for the diagnosis, management, and treatment of medical conditions in a low-cost, scalable way. All healthcare stakeholders will be impacted by the adoption of this technology. In order to engage effectively, clients must be aware of the elements that impact the viability of a digital therapeutic as a partnership, investment, or acquisition opportunity.

Here, we break down these elements into capabilities, mode of action, distribution, and partnerships. These software-based solutions can either augment a form of care to optimize and personalize it for a patient or fully replace a traditional mode of care, such as a pharmaceutical, a physical therapist, or a mental health specialist. They can be accessed either directly from physicians in the form of a prescription, from a payer as a benefit, or via a retail company. As digital therapeutics are small startups in an emerging field, partnerships are crucial to understand in assessing the viability of a company.

Our analysis suggests that of these four elements, provided that there is clinical validation for the therapeutic, it is the partnerships that a digital therapeutic has that are likely to make or break the company.

<table>
<thead>
<tr>
<th>Type of Partner</th>
<th>Research Organizations</th>
<th>Pharmaceutical Companies</th>
<th>Retail Companies</th>
<th>Distribution Specialists</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Strong Positive</td>
<td>Caution</td>
<td>Wait and See</td>
<td>Positive</td>
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LUX TAKE
Why digital therapeutics?

<table>
<thead>
<tr>
<th>Rising Healthcare Costs</th>
<th>Chronic Diseases and Aging</th>
<th>Physician Burnout</th>
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<tbody>
<tr>
<td>Digital therapeutics can address rising health care costs, as the cost of a digital therapeutic subscription can be less than that of a single doctor appointment.</td>
<td>Specialized therapeutics are designed to both diagnose and treat chronic conditions and address the care needs of elderly populations.</td>
<td>Digital therapeutics can reduce the impact of physician shortages, providing optimal, personalized care with fewer physicians.</td>
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</tbody>
</table>

Digital therapeutics fill gaps in the current healthcare paradigm and leverage the increasing desire from physicians and patients for a multimodal approach.
**Digital therapeutics impact current stakeholders**

<table>
<thead>
<tr>
<th>HEALTHCARE PROVIDER</th>
<th>HEALTHCARE PROVIDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>An organization that provides healthcare services</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PAYER</th>
<th>PAYER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any third party that pays for healthcare services</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOLUTIONS PROVIDER</th>
<th>SOLUTIONS PROVIDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>A developer of tools or medications that support one or more stakeholders</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PATIENT/CONSUMER</th>
<th>PATIENT/CONSUMER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipients in the healthcare value chain</td>
<td></td>
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</table>

If current stakeholders do not adapt and adopt these solutions, they risk disruption, as solution providers have the potential to gain a primacy in the healthcare market typically reserved for healthcare providers and payers.
To take advantage of the opportunities offered by startups, players need to understand four things

<table>
<thead>
<tr>
<th>Capabilities</th>
<th>Mode of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital therapeutics are capable of either augmenting a traditional mode of care or fully replacing components of care, including therapists and pharmaceuticals</td>
<td>Digital therapeutics can either work physically on the body or use behavioral change and mental health techniques to psychologically impact the patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Distribution</th>
<th>Partnerships</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital therapeutics can be distributed in a number of ways, ranging from direct-to-consumer sales platforms to pharmaceutically based physician diffusion models</td>
<td>Partnerships in digital therapeutics typically come in one of two flavors, research or distribution</td>
</tr>
</tbody>
</table>
Digital therapeutics can replace or augment modes of care

**Replacement:** Replacement therapeutics directly stand in for a traditional mode of care. They can replace pharmaceutical drugs, physical therapists, and mental health specialists. These features are key for allowing patients to access care:

- If there are geographical barriers to reaching a care provider
- If a traditional mode of therapy doesn’t work for a patient
- If there is a care provider shortage leading to an unrealistic wait time

**Augmentation:** Augmentation therapeutics leverage digital tools like wearables, patches, and other connected devices in order to monitor engagement with a treatment plan. These solutions are usually combined with treatments when:

- The treatment is an expense that needs to be justified to a payer
- The treatment requires a strict adherence regimen that can be difficult for patients to follow
- Data about patient use can augment the treatment regimen

For a comparison of replacement and augmentation and which offers more opportunities, please see [here](#).
**MODE OF ACTION**

**How do digital therapeutics work?**

<table>
<thead>
<tr>
<th>Physical</th>
<th>Psychological</th>
<th>Passive</th>
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</table>
| Physical digital therapeutics treat conditions by acting on patients’ physiology. The techniques used include:  
  - Neuromodulation  
  - Biofeedback | Psychological digital therapeutics use a wide variety of psychotherapeutic techniques, such as:  
  - Cognitive behavioral therapy (CBT)  
  - Gamification  
  - Leveraging neuroplasticity | Digital therapeutics can use passive monitoring as a way to augment therapies by encouraging adherence and sharing data. The key technology is:  
  - Biosensors |

Below: Tivic Health uses neuromodulation to relieve sinus pain  
Below: Litesprite uses gamification to help ease depression and bipolar disorder  
Below: Ossur uses sensors in its prosthetics to optimize limb loss care
There are three broad ways that digital therapeutics get distributed

<table>
<thead>
<tr>
<th>Care Provider</th>
<th>Payer</th>
<th>Retail</th>
</tr>
</thead>
<tbody>
<tr>
<td>The care provider is responsible for distributing the digital therapeutic via a prescription. Care providers can be:</td>
<td>The payer is responsible for distributing the digital therapeutic via its own channels. This may mean:</td>
<td>Consumers bear the burden of learning about and purchasing the digital therapeutic solution. In order to facilitate this, digital therapeutics companies must:</td>
</tr>
<tr>
<td>• Doctors</td>
<td>• Educating clinicians about its availability</td>
<td>• Consider third-party digital dispensaries</td>
</tr>
<tr>
<td>• Psychiatrists</td>
<td>• Making employees aware of the benefits offered in benefit plans</td>
<td>• Share validation data publicly</td>
</tr>
<tr>
<td>• Hospital systems</td>
<td>• Setting up a portal on the insurance member web site</td>
<td>• Have sensitive pricing models</td>
</tr>
<tr>
<td>• Inpatient facilities</td>
<td></td>
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</tbody>
</table>
Within two different types of partnerships, there are four different types of major players

Research Organizations
As their name implies, research organizations like universities and research institutes partner with digital therapeutics in order conduct research. These partnerships allow for the development of the therapeutic through clinical trial resources, test subject opportunities, and data science analytics.

Retail Companies
Retail companies enter into partnerships with digital therapeutics solely to distribute the therapeutic, usually via digital dispensaries.

Pharmaceutical Companies
Pharmaceutical companies partner with digital therapeutics to either develop products by sharing research resources or help in the commercial distribution of digital therapeutics. Commercial distribution partnerships theoretically leverage experience and established distribution channels on the part of the pharmaceutical company.

Distribution Specialists
There has been a rise of distribution specialists serving the pharmaceutical industry for the distribution of specialty drugs for a few years now, and more established digital therapeutics players are finding that these companies are ideally suited for their products.
Partnerships: Retail organizations

Direct-to-consumer retail is very challenging for any healthcare player simply because the expectation is that health products will be paid for by a third party. Tivic Health, which partners with Amazon, is successful, as it is a small, affordable neuromodulation device. Other types of therapeutics, particularly those that are downloadable pieces of software, require digital dispensaries.

Since CVS’s launch of a digital dispensary in 2019, there have been a number of partnerships announced that provide a centralized location for individuals with pharmacy benefit plans to access these programs.
Digital therapeutics present many options, but as long as they meet minimum clinical validation, all choices are valid

**Capability**
While there are often more obvious opportunities for replacement therapeutics as companion programs, sensors and communications companies should not shy away from developing and partnering with the sensors that enable augmentation therapeutics.

**Mode of Action**
Just as there is value in all modes of action in more traditional therapeutics, there is value in all modes of action for digital therapeutics. Any vertical, be it pain, mental health, chronic disease, or rehabilitation, is an appropriate target for a digital therapeutic.

**Distribution**
Depending on the clinical impact of a digital therapeutic, it may or may not make sense to use a traditional pharmaceutical distribution pathway. There is an appropriate level of distribution ranging from prescription products only available through a physician to those available off-the-shelf at a retailer.

**Key Takeaway:** There is no single capability, mode of action, or means of distribution that will indicate the success of a digital therapeutic. Instead, players interested in developing a presence in this space should optimize for what aligns best with their objectives.
How should clients view different partners?

Research Organizations

Partnerships with research organizations should be viewed as a minimum requirement for a good digital therapeutic. These partnerships provide independent clinical validation capabilities, and unless a company is new or being supported in research in other ways, this type of partnership is a positive indicator.

LUX TAKE

Strong Positive

Retail Companies

Partnerships with retail companies are indicators of a distribution strategy in line with a growing trend of decentralized care where the patient will acquire care independently, either paying directly out of pocket or via a pharmacy benefits plan. However, it remains to be seen if this will be a successful strategy or not.

LUX TAKE

Wait and See

Pharmaceutical Companies

Partnerships with pharmaceutical companies can work out well, but they are often risky propositions. Clients should look for digital therapeutics that leverage pharmaceutical companies for research partnerships over distribution partnerships, as those face significant barriers to success.

LUX TAKE

Caution

Distribution Specialists

While these types of partnerships are relatively new, the Pear Therapeutics’ partnership with Envoy immediately improved sales in a way that wasn’t seen with Sanofi, and Cognoa has begun to develop distribution channels – this type of partnership provides what was expected of pharma without the baggage.

LUX TAKE

Positive
Digital therapeutics are a key emerging technology for healthcare
Digital therapeutics are a low-cost, scalable solution that reduces the impact of physician scarcity and improves overall quality of care – but faces challenges in adoption

Digital therapeutics can address any number of conditions in any number of ways
There is no single “best” digital therapeutic approach, and the key to successfully integrating digital therapeutics into a strategy is finding an opportunity that aligns with client objectives

The most important indicator of success is partnerships – especially pharma partnerships
Partnerships are key for this technology to thrive in a traditional established landscape, but special care must be taken with pharma distribution partnerships – they can be a poisoned apple
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