Digital therapeutics
Improving patient outcomes through convergence

Mobile technology is famous for its ability to grab and hold people's attention. Now, a growing number of start-ups and well-established technology companies are betting on that power as a means to help people measurably improve their own health. These players are driving convergence between software and health care in ways that are likely to disrupt how the traditional life sciences industry, which encompasses both large pharmaceutical and medical device (or medtech) organizations, supports the patient health care journey from end to end, giving rise to a new branch of medicine known as digital therapeutics.

What are digital therapeutics?

A novel trend coming out of the fast-growing mobile health (mHealth) market, digital therapeutics are software products used in the treatment of medical conditions. These products are designed to enable patients to take greater control over their care, similar to consumer wellness apps but with one key difference: Digital therapeutics focus on delivering clinical outcomes.

Typically, patients engage with digital therapeutics through mobile apps, including apps that:

- Offer basic guidance, such as techniques to overcome insomnia or administer first aid.
- Work in conjunction with a drug regimen to address more complex conditions—think asthma or cancer treatment.
- Use cognitive or motivational stimulation (often referred to as gamification) to promote behavioral change—which allows drug manufacturers to improve adherence and health care institutions to provide preventative measures that could delay or prevent the onset of a chronic disease.
- Connect with wearables and consumer electronics to track and capture data, as well as communicate with patients.
- Interface with durable medical equipment, such as tracking blood sugar levels, by picking up wireless signals from a sensor embedded in the patient’s skin.

Besides addressing different medical conditions, digital therapeutics can also support various stages of the patient health care journey (figure 1). Along the way, they can collect, synthesize, and analyze patient data so clinicians can personalize treatment and work with the patient to head off complications. The results? Better outcomes and fewer medical interventions.
**Figure 1. Digital therapeutics and the patient health care journey**

<table>
<thead>
<tr>
<th>Patient health care journey</th>
<th>Preventative care and wellness</th>
<th>Diagnosis</th>
<th>Treatment decision</th>
<th>Treatment</th>
<th>High-risk care management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>...enable patients to prevent the onset of diseases through clinically proven well-being and deliberate preventative care activities</td>
<td>...provide diagnostic information to inform patients and health care professionals to make decisions on treatment regimens that improve clinical outcomes</td>
<td>...act as stand-alone treatments with proven clinical efficacy or complement existing treatments by enhancing clinical outcomes</td>
<td>...allow patients and health care professionals to monitor and track symptoms to continually refine and optimize treatment regimens</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Illustrative products</th>
<th>Heart Disease</th>
<th>Breast Cancer</th>
<th>Diabetes</th>
<th>ADHD</th>
<th>Asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital therapeutics deliver clinical outcomes and are focused on specific therapeutic indications such as...</td>
<td>...drive behavioral change through weight, food, and activity tracking followed by interactive coaching and personal challenges</td>
<td>...monitor the breast’s metabolic changes for accelerated cellular activity common in tumor, leading to very early breast cancer detection</td>
<td>...leverage gamification in an application to encourage better glucose tracking habits by rewarding patients</td>
<td>...treat ADHD using a video game to improve children’s attention and inhibitory control</td>
<td>...help people understand current asthma conditions through a set of tools to adjust dosing accordingly</td>
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</table>

Source: Deloitte analysis.
Potential benefits of digital therapeutics

Digital therapeutics are not just a fad. They have the potential to address unmet patient needs that traditional treatments and therapies have been unable to cover. The ability of companies that leverage digital therapeutics to address these gaps, in combination with the much faster product development timelines, could give them a significant advantage over traditional life sciences companies.

The Food and Drug Administration (FDA) recognizes that it must modernize its approach to regulating digital health technology. The FDA launched its Software Precertification (Pre-Cert) Pilot Program in August 2017 to help inform the development of a future regulatory model that will provide more streamlined and efficient regulatory oversight of software-based medical devices. The re-imagined regulatory pathway for software as a medical device (SaMD) products is an acknowledgment that digital therapeutics are a much-needed source of innovation.

For pharmaceuticals and medtech companies, digital therapeutics provide a way to differentiate products with relatively low capital investment, especially compared to R&D costs normally associated with a traditional drug or medical device. Many companies are shifting R&D investments away from core product lines toward transformational innovation. Digital therapeutics also offer an opportunity to extend product life cycles, differentiate products in development, and fill gaps in the market that traditional medicine might not be able to address.

<table>
<thead>
<tr>
<th>Uncertainties and challenges</th>
<th>Market</th>
<th>Channels</th>
<th>Pricing</th>
<th>Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Product definition is unclear to the market</td>
<td>• Patient learning curve may be a challenge as patients adjust to the new user experience</td>
<td>• Physician and health care provider adoption hurdles exist</td>
<td>• Pricing and reimbursement are uncertain due to the nascent state of market</td>
<td>• Regulatory pathway is at the FDA’s discretion</td>
</tr>
<tr>
<td>• Challenge to prove validity until paired with clinical evidence</td>
<td>• Global-scale commercialization strategies of digital therapeutics are unclear</td>
<td>• Health insurance companies may be able to sponsor access or usage of digital therapeutics</td>
<td>• Pricing is expected to diverge from traditional apps and medical treatments</td>
<td>• Analytics and big-data applications face same regulatory path as biomarkers</td>
</tr>
<tr>
<td>• First to market, best consumer experience, and largest user base are critical</td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Anticipated level of disruption</th>
<th>Market</th>
<th>Channels</th>
<th>Pricing</th>
<th>Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Novel product expected to differentiate treatments and provide competitive advantage</td>
<td>• Market is expected to grow significantly, competing with existing life sciences revenues</td>
<td>• Channels for prescription treatments are expected to be similar</td>
<td>• Significantly lower pricing has the potential to disrupt existing pricing strategies</td>
<td>• Approvals will follow novel and unprecedented regulatory pathways</td>
</tr>
<tr>
<td>• Initially expected to be small relative to existing markets</td>
<td>• Initially expected to be small relative to existing markets</td>
<td>• Channels for preventative care are novel for the life sciences industry</td>
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</table>

Source: Deloitte analysis.
Based on Deloitte analysis, the focus on behavioral change is the biggest use-case being explored, with proven clinical success. Nevertheless, there are an infinite number of opportunities on the horizon awaiting clinical validation, requiring further technical development, or needing to be identified and explored by patients and experts in the field.

The potential of digital therapeutics has players across multiple industries weighing their options. Technology giants are interested in developing and acquiring digital therapeutics to enter and change the health care landscape. Payers are exploring whether digital therapeutics can deliver better quality of life and outcomes while maintaining or reducing overall cost of care in certain disease areas, while independently exploring how patient data, which could be collected through such products, can be leveraged to inform coverage. Start-ups are coming up with innovative digital therapeutic ideas to attract investors.

The picture for traditional life sciences companies is somewhat fuzzier. On one hand, a digital therapeutic offering could compete with, and even erode market share for, existing treatments that bring more revenue to the company. On the other hand, digital therapeutics could be an important differentiator—an attractive proposition especially for pharmaceutical companies that have long harbored an ambition to “deliver value beyond the pill.”

Digital solutions are also an opportunity for growth. That’s reflected in the total investment in digital therapeutics, which to date has topped $600 million.

Traditional pharma and medtech companies can make the decision to capitalize on the opportunity presented by digital therapeutics before players in other industries take over. The sooner the entry, the greater the value and growth potential, as first-mover advantage will allow life sciences organizations to define and shape the market.
Deciding what type of solution to offer

Companies that do choose to pursue digital therapeutics could potentially explore two avenues. One is to pursue specific therapeutic areas (TAs). The other is to pursue digital capabilities that are agnostic of TAs (figure 3).

**Figure 3. Digital therapeutics ecosystem**

<table>
<thead>
<tr>
<th>Digital capabilities</th>
<th>Potential to pursue digital use-cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data tracking</td>
<td>Predictive analytics &amp; algorithms</td>
</tr>
<tr>
<td>Communications</td>
<td>Social media</td>
</tr>
<tr>
<td>Sensor services</td>
<td>Virtual reality</td>
</tr>
</tbody>
</table>

**Therapeutic areas**

- Endocrine
- Central Nervous System (CNS)
- Cardiovascular
- Respiratory
- Oncology
- Immunology

**Key:** Maturity of the market (based on number of players)

- Most defined
- Least defined

**TA-focused strategy.** By focusing on a specific TA, pharmaceutical and medtech companies can use their clinical and therapeutic expertise to identify opportunities for introducing digital therapeutic applications. A TA-focused strategy can breathe new life into low-growth TAs—cardiovascular being an example where slower growth in traditional treatment regimens has been projected—via digital therapeutics that complement and differentiate existing offerings. However, this strategy is considered to be incremental rather than transformational, making it more challenging for digital therapeutic initiatives to attract the attention and funding they need.

**Digital capability-focused strategy.** This strategy allows organizations to focus on the art of the possible—that is, look for innovative ways a particular digital capability can be used as a treatment. One example is building a digital application that uses analytics to stimulate behaviors that reduce disease severity. A digital capability-focused strategy is potentially transformational; it could yield offerings that replace existing treatments. However, it can also be harder to execute because it requires bigger investments and a dedicated approach that minimizes distraction from core clinical programs.
Deciding how to build the solution

After deciding on the type of digital therapeutic solution to offer, some pharmaceutical or medtech companies will choose to build the required capabilities themselves. Others will team up with another company to build digital capabilities, access them through an acquisition, or license them from another company (figure 4).

**Figure 4. Digital therapeutics deal decision-making framework**

<table>
<thead>
<tr>
<th>Size of technology company</th>
<th>Desired digital capability</th>
<th>Deal strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>Broad</td>
<td><strong>Complementary pairing</strong> (Partnerships and joint ventures)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pair tech companies’ digital capabilities with Big Pharma’s R&amp;D and regulatory expertise</td>
</tr>
<tr>
<td>Small</td>
<td>Focused</td>
<td><strong>Dominant use-case</strong> (Acquisitions)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Identify a specific use-case to leverage across TAs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Invest in scaling the digital capability across relevant TAs</td>
</tr>
<tr>
<td></td>
<td>Broad</td>
<td><strong>TA app store</strong> (Licensing)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Develop a platform to offer diverse digital capabilities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Create an app store to integrate multiple digital offerings</td>
</tr>
</tbody>
</table>

*Categorization of small (pre-revenue—$25M), Medium ($25M–$5B), and large (>$5B) companies is based on 2017 tech-related revenue.

**Complementary pairing.** Partnerships and joint ventures may make sense if the target company is significantly larger in size, which could make an acquisition financially unviable or strategically unsound. A potential scenario would involve pairing the technical capabilities and digital skillset of a technology company with the R&D and regulatory expertise of a pharmaceutical or medtech company. Because partnerships and joint ventures require a narrow, well-defined scope, they are especially effective for clinical use-cases or unmet patient needs that already have been identified.

**Dominant use-case.** Acquisitions may be appropriate for accessing digital capabilities that stand alone or focus on a dominant use-case. Examples include monitoring health data to identify treatment recommendations and using virtual reality to drive cognitive stimulation. The acquisition route can be particularly effective for smaller companies, as well as for digital therapeutics addressing a small number of indications.

**TA app store.** Licensing is an appealing option for solutions that have a broad range of digital capabilities that can be applied across a life sciences company’s portfolio. For example, a company can license and integrate multiple digital therapeutic products to complement an existing treatment. Although it can limit the company’s ability to define and shape its product, licensing can offer significant flexibility over the longer term.
Putting digital therapeutics into action

Like any innovation, digital therapeutics can present a number of challenges that a traditional life sciences company must address on the way to unlocking their potential. Successfully navigating these challenges will be critical in defining and controlling the adoption of a disrupter like digital therapeutics.

**Challenges include:**

**Mastering the art of the deal.** To the extent that a digital therapeutics initiative involves working with technology partners, companies will likely need to develop cross-industry connections and robust alliance management competencies. Likewise, technology acquisitions will require an ability to find and negotiate deals based on criteria, diligence focus, valuation approach, and terms that fall outside of the usual life sciences acquisition playbook.

**Developing digital capabilities and technology industry expertise.** Life sciences organizations often face a steeper learning curve around navigating the technology space, which can put them at a potential disadvantage compared to technology giants. Life sciences companies need to master incorporating technology products in the R&D pipeline, establishing new trial designs and operational processes (such as technical support), and developing more consumer-focused go-to-market strategies.

**Launching an industry-disruptive product.** Digital therapeutics could put life sciences companies in the position of piloting and defining uncharted territories. Companies must prove the efficacy and increase the adoption of digital therapeutic products without a tested regulatory roadmap within a constantly evolving industry still being defined by regulators. In addition, companies need to work across multiple industries to develop a reimbursement model for digital therapeutics that may differ significantly from existing models.

Digital therapeutics are poised to shift medicine’s emphasis from physically dosed treatment regimens to end-to-end disease management based on behavioral change. This opportunity is drawing nontraditional competitors across industry lines to provide mobile-based solutions in areas that life sciences companies traditionally have served. Pharmaceutical and medtech companies can respond by taking their own bench of health care knowledge into the software territory, where they can co-define the market and capitalize on the growth potential behind digital therapeutics.
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We wish to thank Thuy Le, Michiel ten Broeke, and Christa McKittrick, who contributed their ideas and insights to this project.

Endnotes