How digital therapy benefits patients, providers, and the health ecosystem

Evidence-based, personalized treatment can increase engagement and improve outcomes

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Digital therapy is an emerging approach to effective delivery of behavioral therapy, and fundamentally complementary to pharmacotherapy.

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Talking points

A combination of AI and sensor technologies can augment existing therapy to benefit both patients and healthcare payers

Accumulated patient data enables the creation of individualized solutions. It also allows healthcare providers to optimize treatment with a goal of better outcomes and lower costs.

Life sciences companies are building capabilities commonly found within IT companies, and vice versa

Digital therapy is a useful addition to current standard care. For the life sciences industry, it enables new "beyond the pill" business models centered on support services and advice tailored to the patient.

Proven clinical effectiveness and regulatory oversight are providing guardrails to healthcare's "digital revolution"

Digital therapies must undergo clinical studies, show positive health outcomes, and acquire approval to earn credibility among healthcare providers and payers as an accepted medical treatment.

The future of disease management is digital

Digital products are assuming an ever-greater role in healthcare, from artificial intelligence (AI)-enabled apps that help manage patient health, to digital sensors and wearables that create terabytes of granular data. When it comes to how digital therapy may impact healthcare in the coming years, what stands out are the benefits of personalization and individualization to reinforce healthy behaviors, and the promise of greater patient engagement.[1] And although challenges remain, the healthcare industry is optimistic that digital intervention will improve patient outcomes.[2]

Augmenting therapy with AI and digital sensors

To better understand the potential of digital therapy, consider some of its most valuable clinical applications, such as diabetes and chronic pulmonary disease care, where opportunities to provide true relief currently abound.

More than 400 million people live with diabetes worldwide, and the prevalence is predicted to rise.[3] People with diabetes need to manage their blood sugar levels through lifestyle changes, oral medication, or insulin injection. But optimal daily insulin dosing may constantly vary, which can strongly impact quality of life. AI-enabled capabilities—or the emulation of natural intelligence by a machine—and digital sensors can measure, monitor, predict and respond to daily blood glucose measurements. It can also perform personalized analyses to determine whether and when insulin dose adjustments are needed in real time by identifying when a patient experiences out-of-range highs or lows.[4] Patients whose insulin regime is guided by AI-based software and individualized algorithms might not only achieve blood glucose control more easily but with ongoing personalized dose adjustments, successfully maintain optimal levels long term, and lower their risk of complications.

What are digital therapeutics?

Digital therapeutics, also known as DTx or digital therapy, deliver software-generated interventions directly to patients to prevent, manage, or treat a medical disorder or disease.[5] DTx, like other therapeutic interventions, must demonstrate robust, measurable clinical outcomes, coverage by payers, and regulatory approval.

For life sciences companies, trials become more targeted by identifying patients in need, stratifying the patient population, and using this information for predictive modeling. For payers, targeted treatment in an in-home environment help prevent disease progression. Digital therapy benefits are expected to lead to more accurate treatments for patients, an overall reduction of diseases through prevention and early intervention, and better value-based healthcare models.

Why now?

The exponential decrease in computation costs, the growing capital needed to develop a molecule-based drug, better access to healthcare data, and a strong decrease in sensor technology costs have enabled the delivery of high-quality, clinically validated therapeutic interventions at unprecedented scale. Technological advancements and a new policy landscape will likely lead to a surge in digital health interventions addressing a wider range of health conditions.

Pairing digital sensors and respiratory drugs can also help patients with chronic obstructive pulmonary disease (COPD). A small sensor attached at the top of an inhaler automatically records when a patient uses it. Data is collected and sent to a mobile app to track medication use and—should the patient choose to share their data with a physician—provide personal feedback and insights on how to limit long-term complications. Approved by the US Food and Drug Administration (FDA), the sensor and inhaler combination has shown a 58 percent improvement in medication adherence, 48 percent increase in symptom-free days, and 53 percent reduction in emergency room visits.[6]

Treating human behaviors and human biology

Digital therapy is no match for medicine. It's not a direct replacement for a pharmaceutical intervention, or meant to provide a placebo effect, but may be a useful adjunct to traditional therapy. For those with mood disorders, behavioral change may be less effective than antidepressants. Same for a smoker trying to quit; nicotine replacement may be more beneficial. But a doctor might include a prescription for, say, a mobile app in addition to medicine.

Medication adherence is one of the behaviors that often employ strategies based on cognitive behavioral therapy (CBT), or changing the way one thinks and behaves. CBT is an effective way to treat a range of behaviors and deliver a number of patient therapies, including drug adherence, but it's cumbersome to deliver and often not evidence-based in practice.

Digital therapy can help the healthcare industry meet key objectives by giving doctors personalized diagnostic data to treat patients.

Digital platforms like mobile apps can help encourage and enhance behavioral change with improved access to, engagement with, and quality control of a therapy. For example:

– Sandoz, a division of Novartis and in collaboration with Pear Therapeutics, has commercialized a software-only therapeutic to treat Substance Use Disorder, a disease caused by the recurrent use of cocaine, cannabis, or stimulants.[7] Treatment includes CBT delivered through mobile and desktop applications, monitoring patients in real time, detecting day-to-day behavioral changes, and enhancing treatment outcomes. When used with outpatient therapy and contingency management, it can significantly improve abstinence and retention compared to outpatient therapy alone.[8]

– Digital sleep-improvement program Sleepio seeks to replace sleeping medication with digital therapy delivered through a web-based application. Sleepio uses CBT to help conquer insomnia with coaching to conquer insomnia-related factors like negative thoughts, emotions or behaviors. The therapy also trains positive associations to the sleeping environment and regular bedtime routines. In the first placebo-controlled randomized clinical trial, 75 percent of patients with persistent sleep problems saw an improvement in their sleep.[9]

Blurring the line between treatment and technology

Healthcare professionals who regularly apply or prescribe digitally supported therapy rank individualized therapy and greater patient engagement as primary benefits, along with improved patient outcomes (see Figure 1).

While some digital technologies use cases fall into distinct categories of behavioral modification or therapy augmentation, there are cases that support both. For example, loss of mobility is an ever-increasing concern for both the aging population and post-surgery rehabilitation.

Figure 1

What main benefits will be realized by digital therapies?

63% Individualized therapy

61% Greater patient engagement

56% Improved outcomes

43% Reduced cost of care

30% New medical insights

26% Better reach of care
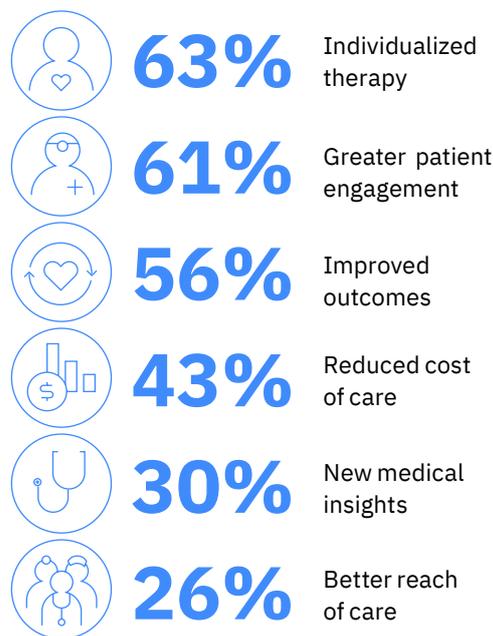
Source: IBM mini pulse survey of healthcare and life sciences professionals in Europe and the US.

Digital solutions can identify, monitor, and motivate patients through natural disease progression, or offer guidance through a treatment and rehabilitation exercise regime. The recovery period can be observed, measured and tracked across platforms. By watching for changes in behavior or physical well-being, such solutions let patients, caregivers and family members see how the patient is doing and enable new treatment approaches with innovative digital therapeutic interventions.

Paramount to ongoing patient monitoring and treatment is developing specific digital endpoints, or digital biomarkers, that measure mobility using sensor data gathered by wearable devices. As pharmaceutical companies experiment with novel wearable technologies, and "health tech" businesses develop medical-grade devices and software, the lines of data ownership become blurred.

Digital therapy can't replace established diagnostic assessments which help establish a cause for disease.

To be competitive in the evolving field of digital health, life sciences companies like Novartis are spearheading digital organizations and building in-house data science capabilities like those commonly found within technical organizations. Likewise, technology companies are taking on capabilities traditionally reserved for life sciences firms, such as building medical devices and running observational studies. For example:

– Two new features of the Apple Watch Series 4—heart monitoring capabilities including electrocardiogram (EKG) and irregular rhythm notification functions, and one that can detect hard falls and summon help if needed—have been cleared by the US Food and Drug Administration (FDA) as a grade 2 medical device.[10]

– Verily Life Sciences, formerly Google Life Sciences, runs Project Baseline, an observational study to track the health of 10,000 participants over time. The goal is to collect comprehensive health data, develop a well-defined reference, or baseline, of good health, and use it as a compass to point the way to disease prevention.[11]

– The worlds of pharmaceutical and technology are also joining forces. Amazon and Merck jointly launched the Alexa Diabetes Challenge, where participants create voice-command technology to help patients with diabetes better manage their disease.[12]

Challenges and the next chapter in healthcare

Regulation is one challenge inhibiting the swift development and creation of digital therapies. Technology is evolving more quickly than the formalization of required legal steps to clinically approve it. Nevertheless, regulations are a crucial prerequisite and must modernize to keep pace with digital innovation. Digital therapies are regulated differently than drugs since they are dynamic and ever-learning. The FDA is developing and implementing strategies, policies, and processes to regulate AI in medical devices.[13]

Then, there's the matter of public perception related to concerns about patient and pharmaceutical data sharing. The General Data Protection Regulation (GDPR) sets stringent guidelines for collecting and processing personal information in Europe, while China and Russia don't allow hosting of data outside their borders. In the US, the Health Insurance Portability and Accountability Act (HIPAA) helps consumers maintain insurance coverage by protecting confidentially.

Digital therapy has yet to show overwhelming commercial results. Accordingly, pharmaceutical companies won't or can't afford to invest without a clear business case on how to commercialize it.

The following is vital to further progress digital therapies:

– Understand what could be improved. Healthcare companies need a firm grasp on information technologies. Pharmaceutical companies need to bolster their scientific and medical strengths with technology, data, and analytics expertise. While partnerships become more important, pharmaceutical companies will have to find the right balance between internalizing core competencies, and bolstering skills and agility through interdisciplinary alliances and external collaborations.

– Explore the potential of digital approaches early. Throughout the development process, life sciences companies need to gather evidence for improved outcomes of digitally supported therapies. Ultimately, they will explore new digital endpoints, generate more comprehensive data, and drive more targeted studies.

– Recognize that people drive technology. Collaboration puts smart people together to create smart solutions. With worldwide technology hubs to share knowledge and leading practices, participation of pharmaceutical companies, scientists, platform and ecosystem players, payers, regulators, and data and analytics specialists and AI pioneers is needed.

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Key questions to consider

» Use cases show that the burden of chronic conditions on both patients and healthcare systems can be elevated with digital therapies. What other areas of healthcare might benefit?

» Obstacles remain that are preventing faster uptake of digital therapies for healthcare. Can these obstacles be overcome?

» How prepared is your industry to unlock the potential that exists between the technology, clinical need, and path to market?

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About Expert Insights

Expert Insights represent the opinions of thought leaders on newsworthy business and related technology topics. They are based upon conversations with leading subject matter experts from around the globe. For more information, contact the IBM Institute for Business Value at iibv@us.ibm.com.

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