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The promise of digital therapeutics

Investments in digital-therapeutics companies in the United States have grown, on average, by 40 percent a year over the past seven years. What lies ahead for this fast-moving sector?

by Austin Hackett, Amy Hung, Olivier Leclerc, and Sri Velamoor

The Promise of Digital Therapeutics conference
was hosted by McKinsey and Digital Therapeutics Alliance, a US-based not-for-profit trade association that aims to broaden the understanding and adoption of clinically evaluated digital therapeutics in healthcare.[1] The conference brought together leaders and other representatives from pharmaceutical and digital-therapeutics companies, payers, and hospital systems to discuss the opportunities and challenges that lie ahead for this fast-developing industry. This article provides some of the key highlights from the conference and discussions on recent developments in digital therapeutics.

The pace of change

Investments in digital-therapeutics companies in the United States have grown by an average of 40 percent a year over the past seven years to reach more than $1 billion in 2018.[2] Investors' enthusiasm mirrors the growing demand for digital-therapeutic products and tools across the healthcare ecosystem—demand that two main trends have buoyed.

First is the technological development that is making available ever-greater amounts of data from which advanced analytics can mine insights. That has enabled the proliferation of personalized hardware, particularly smartphones and wearables. Second, and perhaps more important, is the growing body of evidence that digital interventions work. Peer-reviewed studies show improved outcomes from digital therapeutics, either alone or in conjunction with conventional protocols, in a broad range of indications, including cancer, ADHD, asthma, schizophrenia, and insomnia.[3]

These trends are boosting the utility of digital therapeutics and hence interest in them from all stakeholders in the healthcare system. Patients, accustomed to consumer digital applications, want convenient and informative healthcare products. Physicians, many of whom are digital natives, are keen to manage their patients and businesses digitally. Payers and providers want digital tools that help them serve greater numbers of patients more effectively and at lower cost. Pharmaceutical and medical-device companies are seeking to develop digital solutions that improve current therapies and foster new ones. And the US Food and Drug Administration (FDA), keen to encourage digital innovation in healthcare, is evolving the regulatory framework accordingly.

A glance at some of the start-ups with products coming to market gives a sense of the variety of approaches to healthcare problems that these new digital therapies are utilizing. Products include video games to treat mental- and behavioral-health issues; a digital therapeutic platform that incorporates neurological music therapy, sensors, and artificial intelligence (AI) to help patients who have suffered a stroke or other neurological disorder to rebuild motor skills; and a smartphone app that can conduct electrocardiograms anytime, anywhere.

At the same time, large tech companies are combining their data-gathering and analytic capabilities with their vast scales to develop a new healthcare infrastructure. Amazon's Alexa can diagnose health problems through simple voice commands, for example. Google is applying AI to many areas of healthcare. And Apple is making big advances in health through wearables that allow for continuous monitoring and the integration of

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[1] Debate continues over the definition of digital therapeutics. Digital Therapeutics Association defines them as "evidence-based therapeutic interventions to patients to prevent, manage, or treat a medical disorder or disease." Increasing numbers of industry participants accept this definition.

[2] Digital Health Funding Database, Rock Health, October 14, 2019. rockhealth.com.

[3] Meredith Barret et al., "AIR Louisville: Addressing asthma with technology, crowdsourcing, cross-sector collaboration, and policy," *Health Affairs*, April 2018, Volume 37 Number 4, pp. 525–34, healthaffairs.org; Tom K. J. Craig et al., "AVATAR therapy for auditory verbal hallucinations in people with psychosis: A single-blind, randomised controlled trial," *Lancet Psychiatry*, January 2018, Volume 5, Number 1, pp. 31–40, thelancet.com; Fabrice Denis et al, "Two-year survival comparing web-based symptom monitoring vs routine surveillance following treatment for lung cancer," *JAMA*, 2019, Volume 321, Number 3, pp. 306–7, jamanetwork.com; Daniel Freeman et al., "The effects of improving sleep on mental health (OASIS): A randomised controlled trial with mediation analysis," *Lancet Psychiatry*, October 2017, Volume 4, Number 10, pp. 749–58, thelancet.com; Scott H. Kollins et al, "A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): A randomised controlled trial," *Lancet Digital Health*, February 24, 2020, thelancet.com.

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Regulation and approval for digital therapies

Digital therapies pose unique questions for the regulators charged with approving them. For example, the traditional quality-control measures for drugs, such as strength and purity, clearly do not apply. So what will replace them? What might an appropriate placebo be in clinical trials? What would a digital-therapeutic generic be? And would other elements on which the therapy might depend—perhaps the operating system, connectivity, or the device—also need regulating, and if so, how? Would, for example, a patient whose digital treatment depended on a good internet connection need an approved handset and internet provider?

The changing nature of digital-therapy products is also a consideration. How should regulators approve a product that, by design, will evolve continuously? As digital therapies learn through AI and machine learning, their algorithms will change, which means a product will no longer be the same as the one initially reviewed and approved. When should another review occur? And will regulators consider system improvements as formulations that can extend patent life—and so receive protection

forever? Industry experts talk about digital products moving into a "perpetual Phase IV." As new data accumulates, they will undergo testing against established standards, in ever-more-granular populations, and for new indications. This offers great potential in healthcare, but it also poses a new challenge for regulators.

The FDA, seen as a global leader in tackling the issues that digital therapies raise, is shaping regulation in digital health. It has been receptive to new proposals, to date, and is keen to introduce appropriate regulation. One of the best examples of this is the FDA's Digital Health Software Precertification Program, a pilot for approving software-based medical devices.[4] Conscious of how slow and ultimately unfeasible it would be to approve every software release for a digital product, the FDA uses this program to approve the developer instead. In this way, product development can occur efficiently through rapid iterations, not mired in a constant approval cycle. As of October 2019, the program included nine companies.[5] More will join if the test phase is successful.

Although there are still many open questions, the participants in the Promise of Digital Therapeutics conference felt that the FDA was eager to work with industry to answer them. The message from executives at leading digital-therapy companies for newer companies in the industry was clear: "Engage with the regulators early and often. If you haven't met with them yet, that should be the next thing you do."

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[4] Digital Health Software Precertification (Pre-Cert) Program, US Food and Drug Administration, fda.gov.
[5] The nine companies approved as of October 2019 are Apple, F. Hoffmann-La Roche, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, SAMSUNG, Tidepool Project, and Verily Life Sciences.

Digital-therapy adoption by consumers and healthcare providers

Digital therapeutics come in many varieties, each requiring different strategies to drive adoption. Nevertheless, those that succeed tend to offer three common features: meaningful incentives, human-centered design, and workflow integration.

Meaningful incentives

In a world in which consumers are inundated with information and approaches from companies wanting their attention, companies that offer meaningful incentives are often those that stand out, winning consumers' engagement. McKinsey's 2018 Consumer Health Insights Survey found that the innovative feature of insurance plans most appreciated by consumers was an incentive to change behavior. The majority said they would be willing to change their behaviors—exercise more, for example—to reduce their insurance premiums.

Not all incentives need to be financial. Gamification can be powerful too. A review of studies of digital-health applications showed that those with game-play elements helped improve motivation, engagement, and outcomes in treating arthritis, diabetes, back pain, obesity, and more.[6] Evidence of positive clinical outcomes is another strong incentive that drives uptake and adherence to a therapeutic program.

Human-centered design

Digital-therapy companies must conduct rigorous and continuous user research to ensure that their product designs meet the needs and goals of patients and providers. Not enough do. McKinsey research has shown that users of digital therapies report lower satisfaction and less willingness to recommend the solution to other people than they do when using traditional healthcare products and services.[7]

Likewise, consumers find their experiences with digital therapies lacking relative to the other digital products they use regularly, such as those offered by Amazon, Capital One, and Lyft. Each of those companies focuses on delivering an exceptional user experience based on extensive research, testing, and analytics. Each thinks deeply about the end-to-end experience and constantly evaluates improvements, such as product enhancements and integration with other software products. Digital-therapeutics companies should be aware that their products will be used at just one stage of a patient's healthcare journey. They should therefore identify the other data and products that also form part of that journey and make sure their own products smoothly integrate with them.

Workflow integration

Any digital-therapeutic tool not carefully integrated into clinicians' workflows will face significant barriers to adoption. For example, those that require clinicians to take additional steps to input more information will likely prove unpopular, as will those that require clinicians to shift in and out of different applications. So will those whose results do not integrate with existing patient data—although this issue might become less important as digital natives form a larger percentage of the workforce. By contrast, tools that help clinicians remove even small inefficiencies in their daily tasks will be welcome.

Companies must therefore engage clinicians early in the development process to understand protocols. Omada Health, a company that provides digital therapies used by several healthcare providers to manage chronic diseases, partnered with the American Medical Association to understand how to integrate therapies seamlessly with both clinical workflows and electronic health records.

Partnerships: Attraction and challenges

Successful digital-therapeutics companies have capabilities in areas that many biopharma companies traditionally do not: big data and advanced analytics, hardware engineering, human-centered product design, and innovative, flexible

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[6] Tuomas Alahäivälä and Harri Oinas-Kukkonen, "Understanding persuasion contexts in health gamification: A systematic analysis of gamified health behavior change support systems literature," *International Journal of Medical Informatics*, December 2016, Volume 96, pp. 62–70, sciencedirect.com.
[7] 2018 McKinsey Consumer Health Insights Survey.

business models. Such capabilities will probably prove essential for pharmaceutical companies as healthcare evolves toward a digital future. But an acquisition to bring them in house would likely require significant investment and an appetite for risk, given the number of start-ups that fail. Hence the appeal of partnerships with digital-therapeutics companies instead. Pharmaceutical companies gain access to new capabilities and technologies, and digital-therapeutics companies benefit from greater scale and wider access to providers and patients.

Forging a successful partnership is hard, however. In a survey of digital-therapeutics-industry leaders, participants were asked, "On a scale of one to ten— with ten being "very difficult"—how challenging is it to drive a successful partnership between a digital-therapeutics start-up and a pharmaceutical company?"[8] Eight was the most common response.

The panelists at the Promise of Digital Therapeutics conference shared their top tips, based on their experience, for how digital-therapeutics companies can ensure a successful partnership with a big pharmaceutical company.

— Ensure that operations and offerings can manage the scale-up that comes with a partnership.

— Do not overextend by trying to work with too many companies. Focus on managing a few partnerships well.

— Think of the user experience from the point of view of the partner, as well as of the customer, and design for both parties.

— Align incentives—so that, for example, both partners find the greatest value in the same sales channel.

The pharmaceutical companies that succeed in digital therapeutics may not turn out to be the most innovative, the most digitally capable, or the biggest investors in the industry. Instead, they may be those that are the best partners, striving to smooth the transition for digital start-ups that are working with a large pharmaceutical company for the first time. There are significant advantages to be gained by being the leader in "playing nicely with others."

Who will pay? Reimbursement, value, and business models

The ultimate test of the value of a digital therapy is the amount a customer will pay for it. Among the factors considered, payers will typically value a therapy if given proof that it reduces healthcare costs, particularly by lowering acute-care utilization, reducing complications, or replacing expensive clinician visits with automated software or virtual visits. A proven ability to do any of these raises the likelihood of reimbursement for a digital therapy. Examples of companies attempting to demonstrate this are Myia Labs, whose product strives to reduce emergency hospital visits caused by coronary heart

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[8] Survey conducted at the Promise of Digital Therapeutics conference, with 23 respondents.

disease, and Pear Therapeutics, which aims to move care from the clinic to a cheaper setting.

Employers are interested in enhancements to their employees' experiences with healthcare benefits—and the resulting impact on employee retention—and are thus exploring digital therapies. They also have an incentive to pay for digital therapies that would reduce their medical-healthcare costs and enhance nonclinical outcomes (such as reduced absenteeism and increased productivity) via improved employee health and well-being. Hence the potential appeal of asthma-management products, such as one developed by Propeller Health that uses a sensor attached to an inhaler, along with a mobile app, to help patients stick to their treatment plan and understand what causes flare-ups. According to the US Centers for Disease Control and Prevention, asthma is the leading cause of missed school days for young children and, therefore, a major reason that their parents miss work. The value to employers of increased productivity and reduced staff turnover is the basis on which Happify Health, which offers digital therapies for managing mental health, prices its services.

There is wide consumer interest in healthier living; as a result, some digital-therapeutics products have launched through direct-to-consumer channels.

Examples include the KardiaMobile system; Calm, the meditation and sleep app that has more than one million paid subscribers; and SnoreLab, which monitors snoring and can help identify sleep apnea. However, it is also true that patients with coverage by an insurance policy often have little incentive to pay directly for a digital therapy. One alternative channel that might gain ground, as discussed by the Promise of Digital Therapeutics panelists, is that of a "digital storefront" whereby insurers display vetted applications that they might be willing to subsidize within an insurance plan.

Looking ahead
Developments to date suggest that digital therapeutics in combination with digital-health platforms will swiftly transform the healthcare system. Entrepreneurs will develop new technologies and leverage ideas from every discipline to solve the toughest medical problems. Consumers and providers will become more comfortable with digital therapeutics as product design improves. And regulators will facilitate and provide incentives for innovation. The payers, providers, and pharmaceutical companies that gain experience and build partnerships now will be in the best position to grow with the industry and benefit from the coming waves of innovation.

Austin Hackett is a consultant in McKinsey's Southern California office, where **Olivier Leclerc** is a senior partner and **Sri Velamoor** is a partner; **Amy Hung** is a director of client capabilities in the New Jersey office.