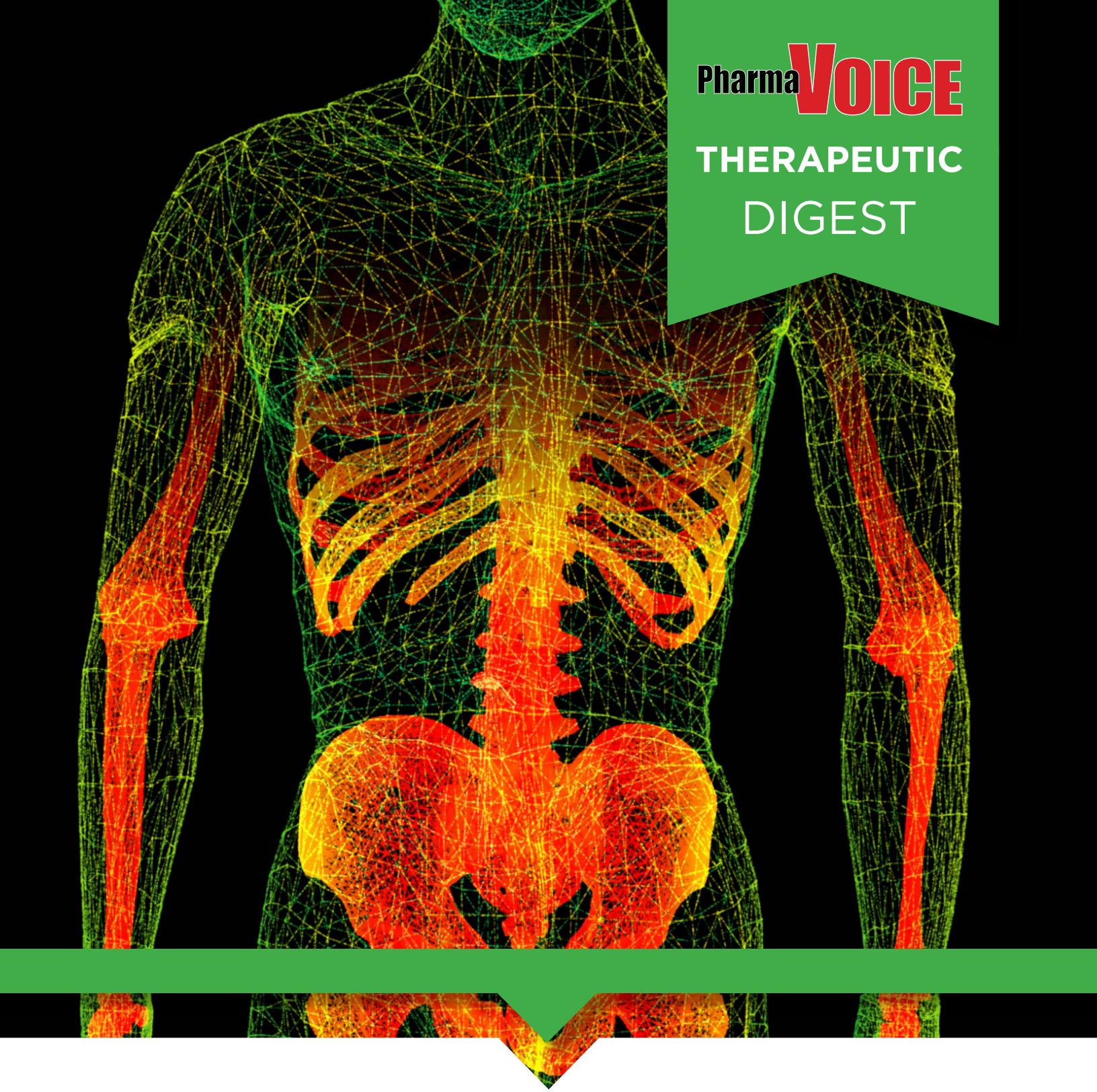


PharmaVOICE

THERAPEUTIC DIGEST

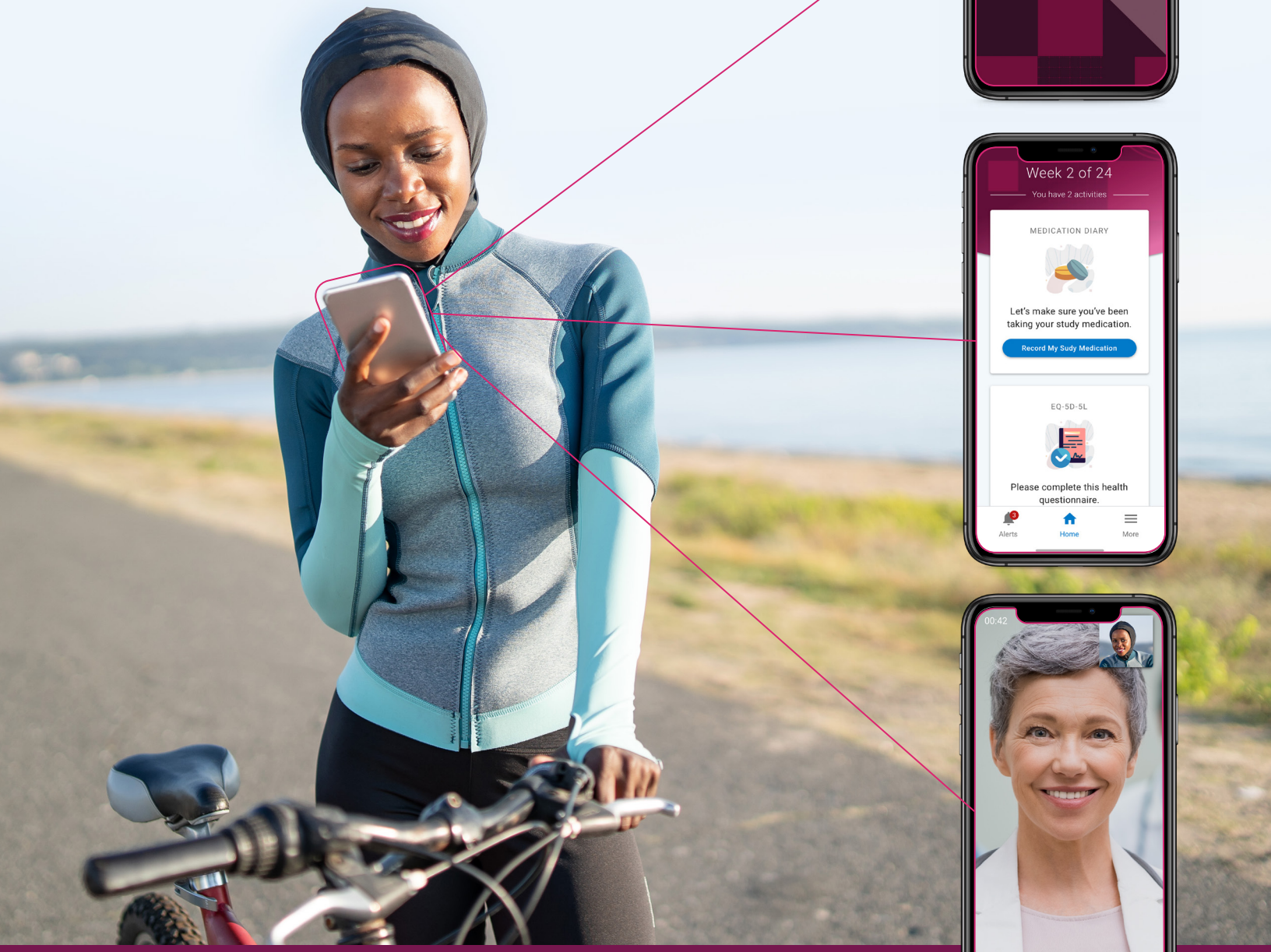
DIGITAL THERAPEUTICS

EXPLORING DIGITAL SOLUTIONS IN THE MODERN AGE OF HEALTHCARE

IN COLLABORATION WITH thinkgen

SEPTEMBER 2020

Clinical Trials.
To Go.



PRA's Mobile Health Platform is how we're integrating clinical trials into the patient's lifestyle. Our platform brings research to patients everywhere they are through their own devices, in their own spaces, and on their own time through decentralized trials. **See how it works at PRAHS.COM/MHP**

Let's Go Mobile.

PRA Health Sciences

Table of Contents

thinkgen Editorial content provided by ThinkGen (www.think-gen.com)
Written by Kristina Erfe Pines

Q&A with PRA's Scott Schliebner

What are some of the specific challenges of running a digital therapeutics clinical trial?

Digital Therapeutics (DTx) are new and different – we're moving away from evaluating a traditional drug or a physical medical device, and instead evaluating software as a medical device or as a therapeutic. This shift changes everything about the way we need to approach a clinical trial. We're not dealing with a chemical or biologic investigational product. We're moving into a space that's novel, not only for regulators and sponsors, but also, thinking downstream about things like commercialization, for payers and their willingness to reimburse. The challenge, right off-the-bat, isn't even about the protocol design of the study. It's about answering bigger foundational questions such as, "How are we going to put this new therapeutic in patients' hands?", and "how do we educate some of the players about this new concept?". We're like pioneers, heading into a space where nothing has been clearly defined. This really is a new frontier.

Regulatory guidance also poses a challenge in DTx trials, as we're not evaluating a drug, but a software setup or an app that we've put in the hands of a patient. This way of conducting research is not as clearly defined from a regulatory perspective. We'll need to work with regulators to understand realistic endpoints and assessments we can make for a DTx trial. I think we're seeing sponsors do the right thing in seeking early consultation with regulatory bodies and continuing to stay engaged with them throughout a digital therapeutics trial, as this is new territory for all of us.

Proving the efficacy of a given digital therapeutic is another challenge. How patients act and use technology in a DTx study at very different than how they would in a controlled study from a physical, investigational site. Until now, we've never truly had insight into what happens once a patient leaves a clinic. Because these studies take place as part of a patient's daily life in their own environment, we must figure out how to manage these new conditions and the real-word data that we're getting from digital therapeutics trials, as we don't have the level of control that we do at a site level.

How are digital therapeutics clinically evaluated?

Evaluating a digital therapeutic is very dependent on the way in which it will ultimately be used, and DTx have a wide range of applications. We've talked with sponsors that have an interactive "chatbot" app that provides a therapeutic intervention that serves almost as a counselor, available to patients as needed. We've talked with clients on the other end of the spectrum, that have AI-guided software that, for example, can make scans more readable and more efficient in detecting something like early cancerous legions. Understanding the focus of a DTx product is essential to evaluating it in a clinical setting. Is the goal to generate data to support claims of risk and efficacy and the intended use? Are we trying to generate some clinical evidence? Are we just trying to make people aware of it so patients can use it? If a client or a sponsor wants to take this process a step further and make claims around efficacy for their product, that changes exactly how we're going to clinically evaluate it and takes us down a more rigorous clinical trial path.

Scott Schliebner
Senior Vice President and
Digital Therapeutics Lead
PRA Health Sciences

PRA Health Sciences

What makes digital therapeutics different from other therapeutics in terms of ongoing analysis and application of real-world evidence and product performance data to ensure continued safety and effectiveness?

The primary difference between a traditional therapeutic and a digital therapeutic is that the latter provides information on usage and interaction in real-time. When a doctor prescribes a medication in a traditional trial, the patient picks it up, and then we don't know exactly what happens next. We only have anecdotal feedback from the patient to understand if they're taking this medication as prescribed, if they're taking it at the right time, if they're taking it with or without food as directed, and so on. Digital therapeutics have a feedback mechanism that can provide that information with precision and in real-time. As opposed to a traditional therapeutic, we're dealing with software. This enables us with the profound ability to generate real-world evidence and insights, and truly understand how people are using this therapeutic in their everyday lives. Considering that we're not manufacturing a pill or a drug, but rather leveraging a software that is, in a lot of ways, a living, breathing thing; DTx will continue to evolve over time. As a digital therapeutic is approved, it's not necessarily going to stay in a "fixed state", as would a traditional therapeutic. These feedback mechanisms – providing real-world evidence in real-time – can help us understand how patients are using a given therapeutic and what's most effective for them. These insights can guide the evolution of a DTx to be more effective and engaging for patients as "version 1.1" becomes "version 1.2". The challenge associated with this evolution is evaluating whether you need to run another clinical study for "version 1.3", for example. ■

Digital Therapeutics

Exploring Digital Solutions in the Modern Age of Healthcare

Digital therapeutics (DTx) are mobile software that digitally deliver clinically proven medical interventions. Unlike lifestyle and wellness apps, they undergo clinical trials and collect real-world outcomes. DTx have emerged in the last few years in a broad range of interventions to prevent, detect, manage, or treat diseases like mental health, cognition, obesity, diabetes, heart disease, respiratory, and many others, sometimes in combination with pharmaceutical products or medical devices (e.g. blood pressure cuffs).

The convergence of conventional pharmaceutical industry with the modern digital technologies is set to open a whole new set of opportunities. Modern pharmacotherapeutic significantly improvises on existing approaches for improving and maintaining the health of the patients. However, controlling the cost of healthcare poses a major challenge for the governments across the globe[1]. Digital healthcare technologies can contribute to reducing the healthcare costs and improve the treatment outcome, especially for lifestyle and chronic diseases[2]. The burden of chronic diseases in terms of morbidity and finances, more so for the developing world, is enormous. A testimony to this is the fact that the U.S. spends 86% of all healthcare costs on chronic diseases every year, and approximately half of the American population is suffering from diseases such as diabetes, heart diseases, obesity, hypertension, smoking, and chronic respiratory disorders[3]. Developing countries such as India and China have the highest incidence of Type 2 diabetes in the world[4]. Therefore, embarking on digital technologies in the healthcare industry can prove to be a shot in the arm for further improving the health of the community.

DTx solutions are growing rapidly worldwide, with an expected annual growth rate of 20.5% over the next six years. According to a report by Allied Market Research the volume of DTx in 2025 will reach $8 billion, with China and the Asia Pacific regions as the strongest areas of growth. The main driving force of the investments will be the need to reduce the risk of health costs, the increasing incidence of chronic diseases among the global population, and the continued concern for face-to-face interactions during the current COVID-19 pandemic, while also helping people with chronic conditions live healthier lives in numerous ways.

WHAT IS DIGITAL THERAPEUTICS?

Sean Duffy, CEO of Omada Health, first used "digital therapeutics" in 2013 to describe its online coaching software to help prediabetics avoid getting sick by exercising more and losing weight[5]. DTx is defined as "a health discipline and treatment option that utilizes digital and online health technologies to treat a medical or psychological condition[6]. " DTx are technology-based solutions in the form of tools such as smartphone applications (app), wearable devices (tracking sensors), web-based studies, social networks, behavioral science, and telemedicine platforms to monitor patient activity and social interaction to detect and intervene when required[7].

Digital therapeutics can claim clinical benefits in three ways[8]:

Digital Services

They modify patient behavior and help in driving a clinical outcome, for example, Omada health's digital behavior platform for weight loss.

Adjunctive Digital Therapeutics

This tier complements traditional therapeutics, indirectly improving the clinical outcome, for example, Proteus Digital Health's Discover medication.

Digital Drug Replacement

They substitute conventional medicine. This requires stringent criteria in terms of clinical trials and the Food and Drug Administration (FDA) review, for example, reSET application for treating substance abuse disorder. A host of companies are collaborating with healthcare providers to shape up various DT programs in different diseases. Most of these initiatives are currently US-based, but emerging trends from countries such as Japan, UK, and India are a positive development.

Difference Between Digital Therapeutics and Wellness Tracking Applications *Table 1*

Category	DTs	Wellness
Indication	Focused on one condition mostly	Focused on various condition
Prerequisite	Regulatory requirement like multicentric RCTs among target population	Minimal technical requirement for downloading from application store
Therapeutic claim	Safe and proven therapeutic value by collection and analysis of real-world evidence	Unsubstantiated claims about clinical benefits
Mode of access	B2B2C	B2C
Key performance indicators	Compliance Prevention of readmission or Repeat intervention in a given amount of time	Number of users Usage Direct turnover
Reimbursement claim	It can be reimbursed by payers depending on DTx compliance	It can only be subscribed by consumers

Abbreviations: B2C- business to consumer, B2B2C- business to B2C, RCTs- randomizes controlled trials
Source: MedKnow

KEY MILESTONES IN DIGITAL THERAPEUTICS

Digital Prescription Program (June 2013)

It was launched by WellDoc with an aim to help diabetic patients manage their condition using a mobile app. Blue Star was the first digital phone app approved by the FDA to manage diabetes[9].

Diabetes Prevention Program

It is a lifestyle modification program for diabetes prevention clinically proven to be more efficacious than lifestyle modifications launched by Omada Health, Canary Health, and Blue Mesa Health. It includes close monitoring of patients in terms of diet, weight, and physical activity and associates them with health coaches, clinicians, or peer groups. This helps to intervene at the time of exacerbations and reduce the frequency of symptoms[10].

Program Aimed to Curb Substance Abuse Disorder

The reSET application developed by Pear Therapeutics[11]. It is a prescription DT used in conjugation with the standard treatment. It claims to improve clinical outcome by increasing patient's adherence to treatment.

List of Various Digital Therapeutic Programs Running Across the World *Table 2*

Program Name	Company	Origin	Domain
DCP	Omada	US	Prediabetics, type-2 DM, hypertension, high cholesterol
Blue Star	Welldoc	US	Type-2 DM
Virta	Virta Health	US	Type-2 DM
Discover Abilify Mycite	Proteus	US	Ingestible sensors
reSET	Pear Therapeutics	US	Substance abuse
reSET-O	Pear Therapeutics	US	Opioid abuse
Thrive	Better Therapeutics	US	Type-2 DM, CHD/CAD, chronic conditions
	Big Health	US	Mental health
	Headspace	US	Stress, insomnia
	IQVIA	US	Healthcare technology and clinical research collaboration
	Kaja Heath	US	Chronic back pain
	Livongo	US	Prediabetics, type-2 DM, HTN
	Merck Innovation Fund	US	Venture capital fund
	Mount Sinai	US	Healthcare system
	NHS	UK	Checkup for stroke, kidney disease, type-2 DM, CAD
	Otsuka	Japan	Digital pill aripiprazole with Proteus
	Propeller Health	US	Digital management of asthma/COPD
muSugr	Roche	US	Type-2 DM, mental health program
	Solera	US	Type-2 DM/ chronic diseases
	Xealth	US	Digital analysis platform
ALKTO 1	Akili Interactive	US	ADHD, autism, depression
PT PAL			Rehabilitation and care
My fitness			Food intake and calories
Stop Cannabis			Cannabis addiction
Asthma MD			Asthma
Workit Health			Addictions
Be Safe			Preventing suicide

Abbreviations: DCP- Dynamic control program, DM- diabetes mellitus, HTN- hypertension, CHD- coronary heart disease, CAD- coronary artery disease, COPD- chronic obstructive pulmonary disease
Source: MedKnow

WHAT SERVICES DO DIGITAL THERAPEUTICS PROVIDE?

Providing Advice on Users' Phones

All DTx products provide active therapies to patients in the comfort of their own homes, and many allow their users to understand and manage their condition themselves. Many companies provide unique services and discretion regarding mental health, sleep problems, and depression. For example, Palo Alto Health Sciences' DTx product, Freespira, has demonstrated success with these patient populations, with a study that shows more than 80% of patients were panic free after treatment[12].

Connecting with Health Coaches

Remote or virtual coaching services are offered by many DTx solutions. These may take place at the time most relevant and through the medium most convenient to the user, including text messages, videos, and chat. For example, companies may utilize health coaching in addition to software to help users manage diabetes. And one of the first U.S. diabetes coaching services, Cecilia Health, provides coaching as well as recommendations for coping and practicing simple, at-home physical activities during the current health crisis. Providing coaching by well-trained professionals can allow DTx companies to greatly reduce any feelings of isolation.

Connecting with Caregivers

Several digital therapies allow for an automated text or call (like Livongo) or an automated alert (like Oleena) to be sent to users or caregivers in case of an emergency, such as a situation involving hypoglycemia.

Automatically Replenishing Supplies

Some DTx are associated with the intake of medicines or the use of medical devices that require consumables (e.g. glucose test strips). Because software allows companies to monitor the actual consumption of these physical products, DTx companies can also identify when a person may be running short on their supplies. The application could then suggest a reorder to be shipped directly to their doorstep. Subscription or membership programs generally offer a fixed monthly price for unlimited consumables. Home delivery of medical supplies has become a vital service for many, positioning Amazon well with its purchase of PillPack[13].

Connecting with Healthcare Professionals

Authorized healthcare professionals may access patient data via their DTx and provide them with their own recommendations.

Offering Telemedicine Functions

According to one article in the New England Journal of Medicine, telemedicine may be a "virtually perfect" solution in times of pandemic[14]. The U.S. president spoke in support of it in March 2020[15]. The Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (DHS) also loosened rules to allow hospitals to use telemedicine[16].

In addition, maintaining a strong pace of clinical trials remains important for developing new treatments for a variety of conditions. Virtual clinical trials, conducted via digital tools, have been happening for some time, including those enabled by technology companies like Obvio Health and Signant Health[17]. The TeleDentists are also helping facilitate emergency dental consultations and virtual visits.

Triaging Patients in Hospitals

This is a different but related area of digital health. Hospitals and DTx can look at ways to connect their own systems and to use patient-reported information to help triage those concerned with situations like the COVID-19 pandemic — a need described years ago during the Ebola outbreak[18].

The goal should be to reduce unnecessary visits to hospitals. For example, Propeller Health says its DTx product for COPD and asthma reduces asthma-related emergency department visits by up to 57%. Among the upcoming software and strategies in this category are Rimidi and its COVID-19 screening app[19], Rx.Health with COVereD, and Providence St. Joseph Health's use of chatbots[20] and nurse lines.

VARIOUS DTx INITIATIVES CURRENTLY UNDERWAY:

Asthma

Asthma was launched by propeller health partnered with GlaxoSmithKline. It consists of a sensor attached with an inhaler to monitor usage and provide feedback. It is used along with medicines and claims that medication needed by the patients is less.

Heart Disease

A physician approved nutritional and lifestyle plan that guides patients to improve their health states launched by Suggestive therapeutics. It monitors physical activity, heart rate, and rhythm[21].

Insomnia

An online therapy program called Sleepio was launched by Big Health which involves visual exercises to induce sleep. It claims to replace sleeping pills, being more efficacious and cost-effective.

Schizophrenia

Thrive digital app launched by Pear therapeutics[22]. It is used along with antipsychotic medication and targets positive symptoms of schizophrenia.

Stress Incontinence

"INNOVO" is the first transcutaneous electrical stimulator launched by Atlantic therapeutics in women to treat stress urinary incontinence. It offers a safe, clinically effective, and noninvasive choice[23].

THERAPEUTIC BENEFICIARIES OF DIGITAL THERAPEUTICS

Chronic debilitating diseases related to behavior can be immediate beneficiaries for DTx. Usually, cognitive behavior therapy is a significant component of their treatment. DTx can offer a solution in terms of a mixture of prevention and therapeutic value. For example, in patients of Alzheimer disease which are expected to rise due to aging population and increased diagnostic awareness, DTx can be very fruitful[24]. Round the clock, monitoring of bipolar and depression patients can improve their quality of life, as psychiatrists cannot monitor a patient 24 hours a day. Such technologies can be helpful in bringing a behavioral change among smokers and alcoholics[25]. These tools have shown a positive impact in patients of HIV and sexually transmitted infections in terms of acceptance[26]. Various applications have been made for efficient and timely management of perioperative patients[27]. Feasibility of these technologies in modern clinical practice clinics, for example, clinical surgery and rehabilitation, is also upcoming[28].

CHANGES IN DIGITAL THERAPEUTICS

Investments in DTx companies in the United States have grown by an average of 40% a year over the past seven years to reach more than $1 billion in 2018[29]. Investors' enthusiasm mirrors the growing demand for DTx 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 DTx, either alone or in conjunction with conventional protocols, in a broad range of indications, including cancer, ADHD, asthma, schizophrenia, and insomnia[30].

These trends are boosting the utility of DTx 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 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, 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 electronic health records to enable patients to view all their data on their phones.

To summarize, it is not hard to imagine the emergence of a very different healthcare system powered by digital technologies within ten years.

DIGITAL THERAPEUTICS REGULATION AND APPROVAL

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[31]. 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[32]. More will join if the test phase is successful.

CONSUMER AND HEALTHCARE PROVIDER ADOPTION

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 [33].

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[34]. 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[35].

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. DTx companies should be aware that their products will be used at just one stage of a patient's healthcare journey. Experts agree therefore that they should identify the other data and products that also form part of that journey and make sure their own products smoothly integrate with them.

Work-Flow 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 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 DTx 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?[36]" Eight was the most common response.

Analysts agree that the pharmaceutical companies that succeed in DTx 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."

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 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.

STEPS TAKEN BY THE FDA

- Approval of the reSET application (1st mobile App) for substance abuse disorder through the de novo premarket review pathway. Furthermore, reSET-O application for opioid use, schizophrenia, and anxiety disorder
- The FDA is running a Pre-Cert pilot program for developing digital healthcare technologies.
- In 2018, 12 healthcare algorithms using artificial intelligence software received FDA clearance[37].
- FDA's Center for Devices and Radiological Health has established the Digital Health Program which fosters collaboration, enhances outreach to digital health customers, and develops and implements regulatory strategies[38].
- The "Digital Health Innovation Action Plan" has been issued which ensures all Americans to have timely access to high-quality, safe, and effective digital health products[39].

CONCLUSION

Digital therapeutics is an emerging field of medicine in the overburdened health systems. Clinical trials are a must to prove their credibility. If used judiciously, they can even improve the treatment outcome. DTx can provide safer and less expensive options than traditional treatment, which, in turn, can save billions of dollars in healthcare, especially in chronic and behavioral disorders. Regulatory authorities are also acknowledging their potential. Policymakers need to make DTx more readily available to the patients by ensuring adequate verification and reproducibility and educating health-care providers and patients regarding the advantages of DTx. From mobile medical apps and fitness trackers to software that supports the clinical decisions that doctors make every day; digital technology can turn out to be a revolution toward affordable healthcare worldwide.

Experts believe that developments to date suggest that DTx 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 DTx 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.

NOTES:

[1] Rana P, Roy V. "Generic medicines: issues and relevance for global health." Fundamental Clinical Pharmacology. 2015.

[2] Sverdlov O, et al. "Digital therapeutics: an integral component of digital innovation in drug development." Clinical Pharmacology & Therapeutics. 2018.

[3] Kvedar JC, et al. "Digital medicine's march on chronic disease." Nature Biotechnology. 2016.

[4] Fleck F. "The mysteries of type 2 diabetes in developing countries." World health organization. Bull World Health Organ. 2016.

[5] Can F. "Digital therapeutics be as good as drugs?" MIT technology review. 2019.

[6] Wikipedia contributors. "Digital Therapeutics." Wikipedia.

[7] Capobianco E. "On digital therapeutics." Frontiers in Digital Humanities. 2015.

[8] Lee D. "Monetizing digital therapeutics." Simon-Kucher and Partners. 2018.

[9] "The present and future of digital therapeutics;" Bioverge. 2018.

[10] "The present and future of digital therapeutics;" Bioverge. 2018.

[11] "FDA permits marketing of mobile medical application for substance use disorder." FDA. September 2017.

[12] "New Freespira study shows nearly 80% of patients are panic attack free at one year post-treatment." https://freespira.com/new-freespira-study-shows-nearly-80-of-patients-are-panic-attack-free-at-one-year-post-treatment/. February 22, 2017.

[13] Lunden I. "Amazon buys PillPack, an online pharmacy, for just under $1B." TechCrunch. June 28, 2018.

[14] Hollander J, Carr B. "Virtually perfect? Telemedicine for Covid-19." April 30, 2020.

[15] "Telemedicine startups see sharp demand driven by coronavirus fears." https://finance.yahoo.com/news/trump-touts-telemedicine-virtual-health-050000365.html. March 13, 2020.

[16] Reuter E. "CMS loosens telehealth laws after national emergency declared for COVID-19." MedCityNews. March 16, 2020.

[17] Lucchini C. "Industry embraces the virtual trial platforms." Pharma World. June 4, 2018.

[18] Mandl K. "EHRs as a public health tool at the point of care." JAMA. December 17, 2014.

[19] Pennic F. "Rimidi launches COVID-19 screening app to identify at-risk patients and limit exposure." HIT Consultant. March 6, 2020.

[20] Lovett L. "Practical takeaways from America's COVID-19 ground zero." Mobi Health News. March 12, 2020.

[21] McConnell MV, et al. "Mobile health advances in physical activity, fitness, and atrial fibrillation: moving hearts." Journal of American College of Cardiology. 2018.

[22] "PEAR Therapeutics and Novartis Collaborate on Digital Therapeutic for Schizophrenia." Open Minds. March 2018.

[23] "FDA grants DeNovo clearance to Atlantic therapeutics for INNOVO therapy device to treat stress urinary incontinence." Business Wire. November 2018.

[24] Tom SE, et al. "Characterization of dementia and Alzheimer's disease in an older population: updated incidence and life expectancy with or without dementia." American Journal of Public Health. 2015.

[25] Webb TL, et al. "Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy." Journal of Medical Internet Research. 2010.

[26] Daher J, et al. "Do digital innovations for HIV and sexually transmitted infections work? Results from a systematic review." British Medical Journal. 2017.

[27] Fotis T. "Digital health and perioperative care." Journal of Perioperative Practice. 2017.

[28] Karpov OE, et al. "Digital technology in clinical surgery and rehabilitation." Khirurgiia. 2017.

[29] "Digital health funding database." Rock Health. October 14, 2019.

[30] Barret M, et al. "AIR Louisville: Addressing asthma with technology, crowdsourcing, cross-sector collaboration, and policy." Health Affairs. April 2018.

[31] Digital health software precertification (Pre-Cert) program. US Food and Drug Administration.

[32] The nine companies approved as of October 2019 are Apple, F. Hoffman-La Roche, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, SAMSUNG, Tidepool Project, and Verily Life Sciences.

[33] Hackett A, et al. "The promise of digital therapeutics." McKinsey & Company. March 2020.

[34] Alahäivälä T, Oinas-Kukkonen H. "Understanding persuasion contexts in health gamification: a systematic analysis of gamified health behavior change support systems literature." International Journal of Medical Informatics. December 2016.

[35] 2018 McKinsey Consumer Health Insights Survey.

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

[37] Muoio D. "Round up: 12 healthcare algorithms approved by the FDA." Mobi Health News. November 2018.

[38] "Digital health innovation action plan." FDA.

[39] "Digital health innovation action plan." FDA.

RESOURCES:

Alahäivälä T, Oinas-Kukkonen H. "Understanding persuasion contexts in health gamification: a systematic analysis of gamified health behavior change support systems literature." International Journal of Medical Informatics. December 2016.

Barret M, et al. "AIR Louisville: Addressing asthma with technology, crowdsourcing, cross-sector collaboration, and policy." Health Affairs. April 2018.

Can F. "Digital therapeutics be as good as drugs?" MIT technology review. 2019.

Capobianco E. "On digital therapeutics." Frontiers in Digital Humanities. 2015.

Daher J, et al. "Do digital innovations for HIV and sexually transmitted infections work? Results from a systematic review." British Medical Journal. 2017.

"Digital health funding database." Rock Health. October 14, 2019.

"Digital health innovation action plan." FDA.

"Digital therapeutics definition and core principles." Digital Therapeutics Alliance. November 2019.

"Digital therapeutics executive Jeffrey Abraham joins Health Advances, bolstering the firm's industry-leading digital health practice." Health Advances. August 19, 2020.

"Digital therapeutics and the future of pharma." Torreya. February 2020.

"FDA grants DeNovo clearance to Atlantic therapeutics for INNOVO therapy device to treat stress urinary incontinence." Business Wire. November 2018.

"FDA permits marketing of mobile medical application for substance use disorder." FDA. September 2017.

McConnell MV, et al. "Mobile health advances in physical activity, fitness, and atrial fibrillation: moving hearts." Journal of American College of Cardiology. 2018.

Fleck F. "The mysteries of type 2 diabetes in developing countries." World health organization. Bull World Health Organ. 2016.

Fotis T. "Digital health and perioperative care." Journal of Perioperative Practice. 2017.

Hackett A, et al. "The promise of digital therapeutics." McKinsey & Company. March 2020.

"Happify Health named to the 2020 CB insights digital health 150 — list of most innovative digital health startups." Biospace. August 13, 2020.

Hollander J, Carr B. "Virtually perfect? Telemedicine for Covid-19." April 30, 2020.

Jarry O. "Digital therapeutics trends and considerations in times of crises." Forbes. April 9. 2020.

Karpov OE, et al. "Digital technology in clinical surgery and rehabilitation." Khirurgiia. 2017.

Khirasaria R, et al. "Exploring digital therapeutics: the next paradigm of modern healthcare industry." Perspectives in Clinical Research. June 2020.

Kvedar JC, et al. "Digital medicine's march on chronic disease." Nature Biotechnology. 2016.

Lee D. "Monetizing digital therapeutics." Simon-Kucher and Partners. 2018.

Lovett L. "Practical takeaways from America's COVID-19 ground zero." Mobi Health News. March 12, 2020.

Lucchini C. "Industry embraces the virtual trial platforms." Pharma World. June 4, 2018.

Lunden I. "Amazon buys PillPack, an online pharmacy, for just under $1B." TechCrunch. June 28, 2018.

Mandl K. "EHRs as a public health tool at the point of care." JAMA. December 17, 2014.

Matzkin A. "How COVID-19 could impact digital health." Health Advances. April 1, 2020.

Muoio D. "Round up: 12 healthcare algorithms approved by the FDA." Mobi Health News. November 2018.

"New Freespira study shows nearly 80% of patients are panic attack free at one year post-treatment." https://freespira.com/new-freespira-study-shows-nearly-80-of-patients-are-panic-attack-free-at-one-year-post-treatment/. February 22, 2017.

"PEAR Therapeutics and Novartis Collaborate on Digital Therapeutic for Schizophrenia." Open Minds. March 2018.

Pennic F. "Rimidi launches COVID-19 screening app to identify at-risk patients and limit exposure." HIT Consultant. March 6, 2020.

Rana P, Roy V. "Generic medicines: issues and relevance for global health." Fundamental Clinical Pharmacology. 2015.

Reuter E. "CMS loosens telehealth laws after national emergency declared for COVID-19." MedCityNews. March 16, 2020

Sverdlov O, et al. "Digital therapeutics: an integral component of digital innovation in drug development." Clinical Pharmacology & Therapeutics. 2018.

"Telemedicine startups see sharp demand driven by coronavirus fears." https://finance.yahoo.com/news/trump-touts-telemedicine-virtual-health-050000365.html. March 13, 2020.

"The present and future of digital therapeutics;" Bioverge. 2018.

Tom SE, et al. "Characterization of dementia and Alzheimer's disease in an older population: updated incidence and life expectancy with or without dementia." American Journal of Public Health. 2015.

"Top 29 digital therapeutics startups." Medical Startups. August 19, 2020.

Webb TL, et al. "Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy." Journal of Medical Internet Research. 2010.

PharmaVOICE

THERAPEUTIC DIGESTS

2020 THERAPEUTIC TOPICS:

Gene Therapy

Mental Health

Alzheimer's Disease

Medical Cannabis

Diabetes

Infectious Diseases

Oncology

Cardiology

Digital Therapeutics

Women's Health

Central Nervous System

Rare Disease