ROUNDTABLE REPORT

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Scrip
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The Emergence of Digital Therapeutics: Building a Future

Brian Harris, Co-Founder and CEO, MedRhythms
Gaurav Laroia, Senior Vice President and Chief Strategy Officer, Biocon Biologics
Corey McCann, President and CEO, Pear Therapeutics
Shuta Mitomo, Head of Digital and Innovation Planning, CRO Business, CMIC Group
Taro Ueno, President and CEO, SUSMED, Inc.
Joris Van Dam, Executive Director and Head of Digital Therapeutics, Novartis
Brent Vaughan, CEO, Cognito Therapeutics
Moderated by: **Ben Comer,** Executive Editor, Informa Pharma Intelligence

KEY TAKEAWAYS

- As digital therapeutic companies develop solutions, they must consider how to deliver value based on patient needs and healthcare economics.
- The power of digital therapeutics lies in delivering care to patients anywhere, anticipating disease progression, and identifying the best interventions.
- Clinical trials for digital therapeutics present different challenges and opportunities from traditional clinical trial programs.
- To determine whether a digital therapeutic needs a prescription, companies must consider the product's benefit-risk profile.
- Thanks to the Medicare Coverage of Innovative Technology (MCIT) final rule, digital therapeutics companies can develop value propositions that look more like drugs.
- Barriers to insurance coverage include benefit design, real-world data, and contracts.

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OVERVIEW

Digital therapeutics (DTx) are evolving rapidly. Many now provide drug-like mechanisms of action that deliver greater value to both standalone solutions and therapies that pair DTx with prescription drugs. To succeed in the market, companies must attract investors, conduct clinical trials, and break down barriers to insurance coverage. Over time, the data collected by digital therapeutics has the potential to unlock predictive and diagnostic information that will enhance patient outcomes.

CONTEXT

A panel of digital therapeutics leaders described the challenges and benefits of different digital therapeutic development models. They discussed regulatory and commercial issues facing the industry, as well as their thoughts about the future.

KEY TAKEAWAYS

As digital therapeutic companies develop solutions, they must consider how to deliver value based on patient needs and healthcare economics.

As the digital therapeutics market has evolved, new solutions have emerged. These include standalone prescription mobile apps that act as therapies, apps combined with prescription drugs, and technologies such as sensors and stimulation devices that treat diseases.

The panelists shared their thoughts about the challenges and benefits of different business models:

- **The market needs both standalone digital therapeutics and digital therapeutics paired with pharmaceutical drugs.** Standalone therapeutics are useful for indications where the benefits and safety profile are superior to a pharmacotherapy, such as some pain treatments. In other instances, it is beneficial to pair digital therapeutics with pharmacotherapies. Examples include pain associated with sickle cell disease or chemotherapy. While both business models are viable, companies must go into them with their eyes wide open.
- **To monetize a digital therapeutic, aspects of the patient journey must be shifted to lower-cost venues and care providers.** This saves money for healthcare systems and increases the likelihood of insurance reimbursement. Biocon Biologics has mapped the patient journey, by disease area, and identified aspects that it can shift to lower-cost treatment models. The company has combined a digital therapeutic with a biosimilar to serve diabetic patients. This is especially relevant for closed loop health systems that care about both clinical and therapeutic costs.

> You must analyze the patient journey and carve out the aspects that can be shifted to lower-cost venues and care providers. When you save money for the healthcare system, you are more likely to be reimbursed.
>
> *Gaurav Laroia, Biocon Biologics*

- **When pursuing a partnership with a pharmaceutical company, DTx providers must consider the relative value contribution of their digital therapy versus the drug.** With insulin therapy, for example, the relative value contribution of shifting insulin dosing to the patient is tremendous. This is appealing to pharmaceutical industry partners. If a digital therapeutic has a low relative value

contribution, however, pharmaceutical companies may divert resources to other pharma projects that seem more attractive.

New digital therapeutics often have drug-like mechanisms of action that create biological changes. These digital therapeutics are no longer simply a value-added service to sell more of a drug. They play an important role in combination therapies. The digital therapeutic may bring as much value to the offering as the pharmaceutical drug.

- **Business model decisions for digital therapeutics must be based on clinical considerations, rather than strategic ones.** Corey McCann from Pear Therapeutics noted that DTx companies must first consider how best to help their target patient populations and then determine the best technology approach. For instance, digital monotherapies are a good option for conditions where FDA-approved drugs don't exist. In other cases, it may be unconscionable to take patients off a drug, so a drug-software combination is more appropriate. In some situations, approved drugs have habit-forming side effects. For these patients, dose titration may be helpful.

The power of digital therapeutics lies in delivering care to patients anywhere, anticipating disease progression, and identifying the best interventions.

MedRhythms' clinical trials have demonstrated that digital therapeutics can deliver drug-like outcomes at scale, regardless of geography, and without the presence of a clinician. This is promising for people in rural areas where physicians and specialists may be hours away.

> The initial patient promise of digital therapeutics is drug-like outcomes at scale in the right geographies. Over time, we will unlock predictive and diagnostic features thanks to the data that we collect.
>
> *Brian Harris, MedRhythms*

It is also possible to collect data from digital therapeutics that can't be gathered from drugs. This can provide greater insight into disease progression, how drugs are working, and what the best interventions are at particular times.

While digital therapeutics can deliver numerous benefits to patients, one challenge is that patients may not understand how to use new technologies. Establishing patient support systems is one of the most important things that DTx companies can do.

> We see several benefits that digital therapeutics deliver compared to traditional drug therapy, such as improved adherence, continuous treatment, and the ability to collect data even when doctors aren't observing patients. On the other hand, a major challenge is educating patients to use the new technologies.
>
> *Shuta Mitomo, CMIC Group*

Clinical trials for digital therapeutics present different challenges and opportunities from traditional clinical trial programs.

The panelists offered insights into the clinical trial process for digital therapeutics:

- **The iterative nature of digital therapeutic development leads to less binary risk than traditional drug development.** With traditional drug programs, a clinical trial failure usually means the end of the clinical program. In contrast, if a digital therapeutic clinical trial fails, it still may provide learnings that enable the company to modify the product. Clinical trials are an iterative step in product development. From an investor or capital allocation perspective, this means digital therapeutics have less binary risk.

> With digital therapeutics, even if the clinical trial fails, it often provides learnings that support iterative product development. From an investor or capital allocation perspective, you see less binary risk around digital therapeutics than with traditional drugs.
>
> *Corey McCann, Pear Therapeutics*

- **Clinical operations issues create challenges.** In digital therapeutics clinical trials, there are many nuances related to how clinicians communicate instructions for use, the way clinicians interact with dashboards, and the quality of the patient onboarding experience. It is difficult to standardize these elements across sites. With COVID-19, most companies are now running fully virtual trials. These provide opportunities to standardize onboarding and clinician engagement. To support remote clinical trials, Pear Therapeutics has built a decentralized platform. SUSMED is also exploring technologies like blockchain to streamline its DTx clinical trials.
- **Within the digital therapeutics space, there is little consensus about the definition of placebo arms.** Digital therapeutics often include hardware and software interactions, as well as stimuli that are provided to patients. Given these various components, teams are often unsure what to placebo for in clinical trials. MedRhythms' product, for example, uses sensors, mobile devices, and music. The company started conducting in-person clinical trials in clinics to reduce the confounding variables. If products will be deployed in homes, however, clinical trials must be run remotely to prove efficacy outside the clinic.

To determine whether a digital therapeutic needs a prescription, companies must consider the product's benefit-risk profile.

When it comes to digital therapeutics, oversight can take many shapes and forms. At one end of the spectrum, patients self-prescribe and self-monitor. At the other end, patients receive oversight from a healthcare provider or physician to ensure that they are using the product appropriately. To determine where on the spectrum a product belongs, companies must be mindful of the target product profile and how it should be used. This will curtail risks for patients, while maximizing the benefits.

Biocon Biologics, for example, offers a digital therapeutic in the diabetes space that requires a prescription. It positioned its product as an acute digital therapeutic that is used in combination with a chronic therapy (i.e., insulin). The company has guided clinician adoption through health systems with integrated payer/provider networks. Reimbursement for its solution comes from two different benefits: drug and clinical. Integrated systems bring those two benefits together.

> A year or two ago, many thought that digital therapeutics were safe, simply because they were apps. We have learned this isn't true. Digital therapeutics can have deep mental and biophysical impacts. To decide whether physician oversight is needed, companies must determine the benefit-risk profile of their DTx.
>
> *Joris Van Dam, Novartis*

Thanks to the Medicare Coverage of Innovative Technology (MCIT) final rule, digital therapeutics companies can develop value propositions that look more like drugs.

In the drug world, FDA approval means physicians will write prescriptions and insurance plans will cover the cost. Typically, when investors from the pharma and biotech sector look at a digital therapeutic device, they remember the thousands of devices with FDA clearance that still have no insurance coverage. MCIT changes that.

The MCIT final rule, which was approved in January, guarantees Medicare coverage for breakthrough-designated devices. If a digital therapeutic is considered a breakthrough device and it falls into an existing benefit category, it will have mandated Medicare coverage on the day of launch. Mandated coverage means that digital therapeutics companies can create value propositions that look more like drugs.

> Our investors are comfortable with digital therapeutics that have value propositions similar to drugs. If people are putting large amounts of money into companies and absorbing clinical and regulatory risks, they don't want to absorb coverage risk on top of that.
>
> *Brent Vaughan, Cognito Therapeutics*

Barriers to insurance coverage include benefit design, real-world data, and contracts.

As the digital therapeutics space has matured, conversations have shifted from the promise of digital therapeutics to discussions about payment structures and benefit design. Historically, these topics have been the "last mile" issue for the industry.

To break down barriers to insurance coverage, Pear Therapeutics is focusing on three areas:

1. **Benefit design.** Ambiguity exists among payers. In some cases, payers will pay for digital therapeutics as a medical benefit, while others will pay as a pharmacy benefit. Since no standard process exists, Pear Therapeutics is going from payer to payer to determine what is most convenient for them.
2. **Real-world data dossiers.** As new digital therapeutics come to market, companies must show the direct cost savings and put proof behind the numbers. Real-world data is required to make products the reimbursable standard of care.

3. **Contracting.** Pear Therapeutics has a team that is writing agreements and contracts with fee-for-service Medicaid organizations, as well as commercial insurers across different employers. There are many moving parts, but the company sees opportunities for portfolio effects. Pear Therapeutics is paving the way with products for addiction, but it is already seeing its chronic insomnia product written into the same contracts.

Japan has a National Health Insurance (NHI) system covering new digital therapeutics. SUSMED has found that the regulatory authority focus mainly on the clinical value when evaluating DTx products. They have not yet incorporated the health economics of treatments into their evaluations.

> In Japan, new DTx is reimbursed under the NHI system. When the regulatory authority evaluate digital therapeutics, they mainly focus on the clinical value. The health economics of the treatment haven't been reflected in the evaluations thus far.
>
> *Taro Ueno, SUSMED, Inc.*

BIOGRAPHIES

Brian Harris
Co-Founder & CEO, MedRhythms

Brian Harris is the Co-Founder and CEO of MedRhythms; a digital therapeutics company focused at the intersection of music and neuroscience. Brian is a board-certified music therapist and one of 350 Neurologic Music Therapist Fellows in the world. Prior to MedRhythms, Brian worked at Spaulding Rehabilitation Hospital in Boston, USA where he created and implemented their first inpatient full time Neurologic Music Therapy program and grew it to the most comprehensive program of its kind in the country. Brian is also the Co-Founder of the Arts & Neuroscience group at the American Congress of Rehabilitation Medicine and sits on the Advisory Council of the Academy of Neurologic Music Therapy. Brian is a sought-after speaker and has delivered presentations and keynotes on music and neuroscience and digital therapeutics at numerous venues around the world.

Dr. Gaurav Laroia
Senior Vice President & Chief Strategy Officer, Biocon Biologics

Dr. Gaurav Laroia is the senior vice president and chief strategy officer at Biocon Biologics, a leading global biosimilar company. He is entrepreneurial enterprise leader skilled at establishing bridges between biotechnology and information technology to democratize access to healthcare. Gaurav has 20+ years of strategic, operational, and management consulting experience in developed (US, EU, Singapore) and emerging markets. He has a deep understanding of the pharmaceutical value chain with experiences across P&L, global marketing, business development, alliance and project management, and R&D. Prior to Biocon Biologics, he held positions of increasing responsibility with Merck, Sanofi, Roche, and McKinsey.

Corey McCann

President & CEO, Pear Therapeutics

Corey M. McCann, MD, PhD, is the president and CEO of Pear Therapeutics, a pioneer in prescription digital therapeutics, as the first company to receive market authorization for software to treat disease. Previously, Corey was an investor with MPM Capital, where he evaluated new healthcare investment opportunities, managed relationships with strategic partners, and oversaw strategy and execution at portfolio companies. Prior to MPM, he was an engagement manager with McKinsey & Company, where he advised pharmaceutical, medical device, and biotechnology companies on the acquisition, development, and commercialization of life science technologies. He led McKinsey's central nervous system expertise group, advising clients across the healthcare value chain.

Shuta Mitomo

Head of Digital and Innovation Planning, CRO Business, CMIC Group

Mr. Shuta Mitomo has over 20 years' experience in clinical development. Prior to joining CMIC, Shuta worked in a global pharmaceutical company for over 14 years. He has over eight years of project management experience in CROs, working with various global/local pharmaceutical companies and other service providers. He has managed many clinical trials as a project manager, including in-country clinical caretaker (local agent for clinical trials in Japan), leading the global sponsors to develop their drugs in Japan successfully. Shuta is currently the head of digital and innovation planning in CMIC Group's CRO business and is responsible for implementing new digital technologies in clinical trials.

Taro Ueno, Ph.D.

President & CEO, SUSMED Inc.

Dr. Taro Ueno founded SUSMED in 2015. His expertise is in sleep medicine, neuroscience, and digital medicine. Before founding SUSMED, he did medical research as a principal researcher at Tokyo Metropolitan Institute of Medical Science. He also worked as a medical doctor in hospitals. He has published over 20 scientific papers and 10 patents. He received the Inoue Research Award, Scholarship by The Naito Foundation and Grant in Aid from Takeda Science Foundation. Since 2017, Taro has also served as a counselor of The Japanese Society of Sleep Research. He graduated from Tohoku University school of Medicine and obtained his Ph.D. from Kumamoto University.

Joris van Dam

Executive Director, Head of Digital Therapeutics, Novartis

Joris van Dam is a digital health intrapreneur with 17 years' experience in pharmaceutical research and development, focusing on the innovative use of digital technologies to improve and transform therapeutic innovation, patient engagement, and clinical trials operations. Joris is currently leading the digital therapeutics initiative at Novartis Institutes for BioMedical Research, where he led the partnership with Pear Therapeutics. Prior to that, Joris launched a number of digital health innovation

initiatives at Novartis, including the Trials of the Future program, the Patients-2-Trials Consortium, the Clinical Research Collaboration with Walgreens, TriNetX, CentrosHealth, and a mobile platform for bedside data collection for clinical trials in Africa.

Brent Vaughan
CEO, Cognito Therapeutics

Brent Vaughan is CEO of Cognito Therapeutics, a clinical-stage company leading the development of a new class of disease-modifying digital therapeutics to treat neurodegenerative disorders including Alzheimer's disease. With more than 20 years of experience, he has a proven track record of success developing proprietary technologies and products across multiple domains, including digital therapeutics, medical devices, and pharmaceuticals. Prior to Cognito, Brent was chief executive officer and co-founder at Cognoa, an AI-based digital therapeutics company, where he established the company as a leader in digital therapeutics and pediatric behavioral health.

Ben Comer
Executive Editor, Infprma Pharma Intelligence (Moderator)

Ben brings both biopharma expertise and diverse experience. For the past five and a half years, he was a senior manager in PwC's Health Research Institute. He developed reports on various policy issues and business trends, particularly in the pharma and medtech sectors, provided research for clients, and spoke at industry events. Previously, he was a journalist with *Pharmaceutical Executive*, *Medical Marketing & Media*, *PRWeek*, and *Direct Marketing News*.

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