

Digital Therapeutics Strategic Partnerships SUMMIT

Dive deep and collaborate with digital innovators for tactical solutions and lessons learned in strategic partnerships, commercial models, regulatory pathways, and data standards.

Featured Speakers



Chris Wasden, Ed.D.,
Head, Pharma,
HAPPIFYDTX



Barbara Eichorst,
Global Diabetes and Digital
Therapeutics Clinical
Liaison,
VOLUNTIS



Edward Cox,
CEO,
DThera Sciences



Adam Kaufman,
President and CEO,
CANARY HEALTH



Dave Conn,
COO,
GLOOKO



Debra Reisensthal,
Founding CEO, Freespira
Digital Therapeutic,
**PALO ALTO HEALTH
SCIENCES**



Vincent Hennemand,
SVP, Strategy, Corporate
and Business Development,
**AKILI INTERACTIVE
LABS**



Jennifer Goldsack,
Interim Executive Director,
DIME SOCIETY



Mette Dyhrberg,
Founder and CEO,
MYMEE



Kevin McRaith,
CEO and President,
WELLDOC



Mark Bini,
Vice President, New
Solutions,
EXPRESS SCRIPTS



Ryan Sysko,
CEO,
AMALGAMRX

Conference Co-Chairs



Joel Sangerman,
Chief Commercial Officer,
CLICK THERAPEUTICS



Ruchita Sinha,
Senior Director of Investments,
SANOVI VENTURES

Special Focuses



→ **Understand** the importance of strategic partnerships



→ **Explore** innovative commercial models



→ **Discuss** developing regulatory pathways



→ **Pinpoint** strategies for data management



→ **Enhance** multi-stakeholder collaboration

WHO SHOULD ATTEND

This conference is designed for professionals from digital therapeutics, pharmaceutical, biotech, and medical device companies with responsibilities in the following areas:

- Digital Therapeutics
- Digital Health
- Digital Medicine
- Digital Strategy
- Tech Development
- Commercial Strategy
- Market Access
- Commercialization
- Personalized Healthcare
- Medical Devices
- Combination Products
- Product Development/Management
- Medical Affairs

This conference is also of interest to:

- Digital Health Software Developers
- Data Management Service Providers
- Technology and Digital Solutions Providers
- Investment and CV Firms

Dear Colleague,

Digital Therapeutics represents an opportunity to capitalize on technology and efficiency while delivering an elevated standard of care to patients. The innovation of digital therapeutics will enable the population to monitor and manage their healthcare as well as prevent diseases and improve their patient outcomes. This is a critical time for the industry, as guidelines are put in place, and best practices are being developed.

The common goal of digital therapeutics is to create effective treatments that could potentially replace drugs or improve patient outcomes in combination with existing drugs. However, misaligned incentives of key stakeholders are making the shift towards digital therapeutics a challenge. In order to advance the industry, it is critical for digital therapeutics owners, healthcare providers, payers, and pharmaceutical organizations to come together and create mutually beneficial partnerships. As innovative companies are paving the way in this industry, there are many strategies and topics to be discussed between the above-mentioned stakeholders, including:

- Market Access
- The New Commercial Model
- Regulatory Pathways
- Partnership Opportunities and Strategies
- Clinical Validation
- Data Management and Communication

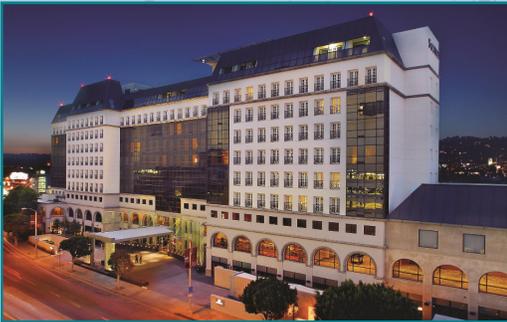
The Digital Therapeutics Strategic Partnerships Summit is designed to be a meeting of the stakeholders, featuring real case-studies and lessons learned, to foster collaboration and ensure a common goal is defined. It is vital to have decision-makers from each stakeholder segment represented and present as they dive into their organization's experiences. The purpose of this Summit is to provide tangible resources while discussing standards for regulatory pathways, the benefits of strategic partnerships, and the importance of data sharing and governance. The Summit will focus on collaborating, educating, and strategizing as an industry.

I look forward to welcoming you, your peers, and the expert speaking faculty to this collaborative program in Los Angeles this November.

Sincerely,

Brianna Conetta

Brianna Conetta
Associate Conference Production Director



VENUE INFORMATION

Sofitel Los Angeles at Beverly Hills
8555 Beverly Blvd / Los Angeles, CA 90048

To make reservations, guests can call 1-800-521-7772 or 310-278-5444 and request the negotiated rate for "ExL's November Meetings." You may also make reservations online using the following weblink: <https://tinyurl.com/y46qbfnk>. The group rate is available until **October 20, 2019**. Please book your room early, as rooms available at this rate are limited.

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8:00 Registration and Continental Breakfast

8:45 **Co-Chairpersons' Opening Remarks**

Joel Sangerman, *Chief Commercial Officer*, **CLICK THERAPEUTICS**

Ruchita Sinha, *Senior Director of Investments*, **SANOFI VENTURES**

9:00 **KEYNOTE ADDRESS**

Take a Deep Dive: Change, Adoption, and Innovation in the Digital Therapeutics Industry

The Digital Medicine Society (DiMe) is the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. Together, we drive scientific progress and broad acceptance of digital medicine to enhance public health.

- Discuss the current landscape of the industry
- Define some of the key issues that will be addressed at this conference
- Gain an understanding of the different stakeholders in attendance
- Set a precedent for collaboration with the audience and industry as a whole

Jennifer Goldsack, *Interim Executive Director*, **DIME SOCIETY**

MARKET ACCESS

9:45 **STAKEHOLDER PANEL**

Digital Therapeutics: The NEW Commercial Model

- Discuss traditional commercial models in the pharmaceuticals/med device industry
- Explore the characteristics of digital therapeutics that challenge conventional commercial pathways
- Create adaptations that meet the needs of the digital market
- Pinpoint new opportunities and challenges associated with innovative digital therapies

Mette Dyhrberg, *Founder and CEO*, **MYMEE**

10:30 Networking Break

11:00 **Looking Ahead: Exploring Regulatory Pathways for Digital Therapeutics**

Dthera Sciences is a publicly-traded digital therapeutics company focused on the elderly and individuals with neurodegenerative diseases. Dthera's DTHR-ALZ is the first product to receive Breakthrough Device designations from the FDA for the treatment of Alzheimer's disease.

- Discuss current limitations of the regulatory landscape when bringing a new digital therapy to market
- Pinpoint process development challenges that are specific to digital medicine and understand how the regulatory landscape impacts that
- Review the latest updates from the pre-cert program and how they impact digital therapeutics
- Explore the pathways that lie ahead and the expedited timeline that comes with a rapidly changing industry

Martin Culjat, *SVP Scientific and Regulatory Affairs*, **DTHERA SCIENCES**

11:45 **Leveraging a Digital Therapeutic Patient Platform: Managing and Treating Patients With Sanofi**

HappifyDTx is a digital therapeutic company that addresses anxiety and mood disorders, which are comorbid with most chronic diseases pharma companies treat. HappifyDTx's RCTs with over 2,000 participants and commercial contracts with the largest health plans and employers in the U.S.-led Sanofi to seek a partnership.

- Understand why digital therapeutics is critical to the next phase of evolution in the pharmaceutical and biotech industry
- Analyze partnerships at the center of the strategy
- Discuss the diverse partnership relationship spanning R&D, clinical trials, regulatory approval, commercialization, and follow-on patient and technology support

Chris Wasden, Ed.D., *Head, Pharma*, **HAPPIFYDTX**

12:30 Luncheon



- 1:30 **Lessons Learned: Partner With Clinicians for Digital Therapeutics Integration**
 Digital therapeutics is part of insulin titration. Electronic glycemic management systems and FDA-cleared apps help providers and people with diabetes to optimize care and outcomes.
- Explore the process of patient integration through clinical education
 - Understand the usual workflow for clinicians and how to integrate digital therapeutics into their process
 - Pinpoint strategies to advance clinical inertia with the help of providers
 - Institute digital therapeutics as a part of patient education and interventions
- Barbara Eichorst**, *Global Diabetes and Digital Therapeutics Clinical Liaison*, **VOLUNTIS**
Laurel Fuqua, *Executive VP and Chief Clinical Officer*, **MONARCH MEDICAL TECHNOLOGIES**

PARTNERSHIPS

- 2:15 **Lessons Learned: The Many Journeys to Partnership**
 As part of Canary Health's pioneering work in digital therapeutics, the company has partnered with manufacturers, health plans, providers, population health companies and other digital therapeutics companies
- Analyze several case studies of partnerships across the ecosystems
 - Determine value for various organizational types and basis for partnerships
 - Discuss opportunities and pitfalls in partnerships
 - Explore some lessons learned in the process
- Adam Kaufman**, *President and CEO*, **CANARY HEALTH**
- 3:00 Networking Break
- 3:30 **Partnering to Enable New Business Models: The Need for Novel Partnership Modalities**
 As part of their close collaboration for the development and the commercialization of Akili's lead product in ADHD for the Japanese and Taiwanese markets, Shionogi and Akili recently executed a unique partnership model to leverage their respective expertise and capabilities toward a dually-owned commercialization path.
- A different licensing/partnering mindset: A jointly owned operational model across the two partners
 - Identifying and leveraging the respective core expertise and capabilities to deliver on DTx products
 - Identifying and bridging "gaps" in mindset and experience
 - Lessons learned in managing market and regulatory specificities
- Vincent Hennemand**, *SVP, Corporate and Business Development*, **AKILI INTERACTIVE LABS**
TBD, **SHIONOGI**
- 4:15 **Collaborating With a Payer: Explore the Process From Medical Policy to Commercialization**
 Highmark Health (HH) is a 5.5 Million member BCBS Plan in Pennsylvania, Delaware and W. Virginia. Hear about Palo Alto Health Sciences' experience in working with HH to demonstrate the clinical outcomes and financial savings when treating members with the Freespira digital therapeutic and how the partnership drove the utilization of Freespira once the medical policy was in place.
- Explore a health economic study that validated clinical and cost outcomes
 - Determine alignment on strategic goals between PAHS and HH
 - Marketing to develop a win-win marketing campaign for Freespira
 - Tactics employed post medical policy to educate members and the hurdles that were overcome to gain adoption with providers and their staff
 - Take a look at marketing campaign results
 - Analyze challenges and lessons learned
- Debra Reiselthel**, *Founding CEO, Freespira Digital Therapeutic*, **PALO ALTO HEALTH SCIENCES**
Matthew Tucker, *Director of Strategy and Innovation*, **HIGHMARK HEALTH**
- 5:00 **Prescription Software Distribution and Reimbursement: Partnering for Success**
 There is growing recognition that digital medicines, based on clinical efficacy, can improve patient outcomes, fill gaps in access to care, and lower costs. A leading specialty pharmacy and developer of digital medicines in pediatric behavioral health will discuss the market forces, necessities, and collaborations that will commercialize these solutions as they become increasingly mainstream.
- Hear from two industry stakeholders on how they are revolutionizing the distribution of digital medicines
 - Discuss how partnerships can seamlessly integrate the management of digital medicines into the healthcare workflow
 - Analyze the larger macro-landscape challenges of the digital therapeutics industry
 - Strategize with partners to recursively enhance supply chain logistics and reduce costs
- 5:45 Day One Concludes

8:00 Continental Breakfast

8:45 **Co-Chairpersons' Recap of Day One**

Joel Sangerman, *Chief Commercial Officer*, **CLICK THERAPEUTICS**

Ruchita Sinha, *Senior Director of Investments*, **SANOFI VENTURES**

9:00 **Exploring Scalability: Discuss Models for Creating Scale in Digital Therapeutics**

Dthera Sciences is a publicly-traded digital therapeutics company focused on the elderly and individuals with neurodegenerative diseases. Dthera's DTHR-ALZ is the first product to receive Breakthrough Device designations from the FDA for the treatment of Alzheimer's disease.

- Understand the importance of creating scale
- Discuss the benefits of integrating operations on a larger scale
- Pinpoint common challenges faced by digital therapeutic organizations
- Explore various partnerships that enable organizations to create scale

Edward Cox, *CEO*, **DTHERA SCIENCES**

9:45 **Big Pharma As a Strategic Partner: Developing Strategic Digital Health Opportunities**

As a pioneer in digital health, WellDoc cuts through the noise by understanding the leading routes to market and partnership models for digital therapeutic commercialization.

- Explore the criteria being evaluated when discussing partnership opportunities
- Analyze the process of defining a common goal for your strategic partnerships to selectively advance your business model
- Communicate the value of your digital therapeutics software effectively when negotiating partnerships

Kevin McRaith, *CEO*, **WELLDOC**

DATA & VALIDATION

10:30 Networking Break

11:00 **Payer Perspective: Digital Therapeutics Validation**

Express Scripts, a Cigna company, unlocks new value in pharmacy, medical and beyond to further total health for all. Its industry-first, stand-alone digital health formula helps payers ensure the safety, effectiveness, and usability of digital health technology tools made available to their members.

- Understand the importance of clinically validating digital therapeutics
- Pinpoint pathways to partnerships that increase efficiency for all stakeholders involved
- Explore the benefits of decreasing costs and creating scale
- Develop a new standard for market entry in digital therapeutics

Mark Bini, *Vice President, Innovation and Member Experience*, **EXPRESS SCRIPTS**

11:45 **Real-World Evidence: Understand the Value of Developing RWE in Digital Therapeutics**

The Learning Corp is the creator of the award-winning Constant Therapy app that uses AI to help people recover their brain function after a stroke, brain injury, or other neurological disorders. Constant Therapy has won awards from the American Heart Association and AARP for its patient impact.

- Pinpoint the importance of developing real-world-evidence in digital therapeutics
- Design considerations in developing real-world evidence while building digital therapeutics products
- Discuss the best practices in collecting and analyzing RWE
- Analyze examples of retrospective studies showing RWE collected during clinical trials

Veera Anantha, *Founder, CTO and President*, **THE LEARNING CORP**

12:30 Luncheon

1:30 **Data and Privacy: Who Owns the Data and What Can They Do With It?**

Diabetes management requires data from multiple sources to be viewed in a combined manner for insights and pattern recognition for safe and appropriate treatment decisions. Digital therapeutic apps can reduce this burden, but to be successful, they need access to data to create the proper recommendations.

- Discuss different levels of device and platform interoperability
- Describe what "ethical handling of patient data" encompasses
- Explore how interoperability is critical for "value-based care" and population management
- Discuss scenarios that describe effective use cases of the interoperability that meet the needs of busy diabetes clinics

Dave Conn, *COO*, **GLOOKO**

2:15 **Understanding Challenges and Creating Solutions: Build a Body of Clinical Evidence for Digital Solutions**
 Amalgam's leading the charge to improve clinical and behavioral outcomes for chronic disease management. We're changing population health into personalized care by combining traditional therapies with best-in-class digital interventions.

- Walk through the journey of building a body of evidence for digital therapeutics
- Explore the differences in digital clinical trial design as opposed to traditional pharma models
- Reference the World Health Organization's model for designing studies
- Discuss pathways to validation and common obstacles

Suzanne Sysko Clough, M.D., Chief Medical Officer, AMALGAMRX
Ryan Sysko, CEO, AMALGAMRX

3:00 **Stakeholder Panel**
Clinical Data, Validation, and Evidence: Understand Industry Goals and Methods

- Discuss the challenges and common obstacles faced by Digital Therapeutic startups when beginning the clinical validation process
- Understand the motivation, importance and potential regulatory pathways associated with clinically validated therapeutics
- Explore validation from various stakeholder perspectives; what makes validation relevant and useful in the eyes of differing stakeholders
- Recognize the relationships between clinical validation and commercial value

Alan Gilbert, CEO, BECARELINK

3:45 **Co-Chairpersons' Closing Remarks**
Joel Sangerman, Chief Commercial Officer, CLICK THERAPEUTICS
Ruchita Sinha, Senior Director of Investments, SANOFI VENTURES

Registration Fees for Attending ExL Events' Digital Therapeutics Strategic Partnerships Summit

EARLY BIRD PRICING	STANDARD PRICING	ONSITE PRICING
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\$1,895	\$2,095	\$2,195

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