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December 4-5, 2019 | Boston, MA

clinicallyvalidated-dtx.com

Clinically Validated Digital Therapeutics

Design, Develop & Deliver Regulated & Clinically Validated Digital Therapeutics to Patients in Need, Now

Expert Speakers Include:

Matthew Tucker
Director, Enterprise Strategy & Innovation
Highmark Health

Shrawan Patel
Vice President & Head, Clinical Transformation
Rx.Health

Megan Coder
Executive Director
Digital Therapeutics Alliance

Maria Latushkin
Senior Vice President, Engineering
Omada Health

Martin Culjat
Senior Vice President, Scientific & Regulatory Affairs
Dthera Sciences

Joel Sangerman
Chief Commercial Officer
Click Therapeutics

2019 Partner: Innovenn®

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Welcome to Clinically Validated Digital Therapeutics Summit 2019

Back even more scientifically stringent, the 2nd **Clinically Validated DTx Summit** is dedicated to the development, commercialization and integration of **evidence-driven digital therapeutics.**

Uniting pharma, DTx companies and healthcare institutions, Clinically Validated DTx Summit is solely focused on the **actionable uses** of digital therapeutics to **deliver radically improved patient outcomes**.

Tackling a multitude of disease areas and therapeutic modalities, Clinically Validated DTx Summit will link R&D innovation to the tangible sustainment of the DTx industry and host clinical and medical data to **move beyond the future-focused hype**. Shifting to the **current real world application** of DTx, this summit integrates advocacy for the progression of collaboration, partnering and evolution of business models to the benefit these therapeutics can bring to patients worldwide.

Hear what previous attendees have to say

"Clinically Validated Digital Therapeutics Summit was the most worthwhile conference I've been to. There were excellent speakers, debates and it was a pleasure to attend"

Senior Global Digital Director, **GSK**

"Right off the bat, the inaugural conference on 'Clinically Validated Digital Therapeutics' brought together a high quality, deeply engaged audience that is at the core of the Digital Therapeutics movement"

Head of Digital Therapeutics, **Novartis Institute for Biomedical Research**

Key Case Studies in 2019:

Robust validation and trial design, from effective placebos to user experience, with insight from **Akili**, **GSK**, **DarioHealth** & **Novartis**

Integration into the complex healthcare system for routine physician use with leading expertise from **GAIA AG**, **Rx.Health** & **WellDoc**

Navigating the regulatory landscape with **Dthera Sciences** to effectively achieve FDA designation and unlock future growth opportunities

Leveraging partnerships, develop internal commercial strategies and understand the reimbursement landscape to break through the market with **Click Therapeutics** & **Highmark Health**

Putting the consumer first by ensuring the safety and privacy of patient data in DTx development with **Omada Health**

"The event brought together leaders from the digital therapeutics space. It enabled everyone to have an open and honest discussion about the challenges we're facing, and importantly, how to come together and positively shape our industry!" **Founder & Managing Director, Volar Health**

YOUR EXPERT SPEAKERS

Mark Bini
Vice President, Innovation & Member Experience
Express Scripts

Megan Coder
Executive Director
Digital Therapeutics Alliance

Martin Culjat
Senior Vice President, Scientific & Regulatory Affairs
Dthera Sciences

Mary Dixon
Chief Executive Officer & Founder
Innovenn

Kai Gait
Senior Global Digital Strategy Director
GSK

Aaron Gani
Founder & Chief Executive Officer
BehaVR

Chris Hogg
Chief Commercial Officer
Propeller Health

Anand Iyer
Chief Strategy Officer
WellDoc

Olivier Jarry
Chief Commercial Officer & President
DarioHealth

Anil Jina
Chief Medical Officer
Akili

Adam Kaufman
Co-Founder, Chief Executive Officer & President
Canary Health

Maria Latushkin
Senior Vice President, Engineering
Omada Health

Eddie Martucci
Founder & Chief Executive Officer
Akili

Shrawan Patel
Vice President & Head, Clinical Transformation
Rx.Health

Joel Sangerman
Chief Commercial Officer
Click Therapeutics

Matthew Tucker
Director, Strategy & Innovation
Highmark Health

Joris van Dam
Head, Digital Therapeutics
Novartis

Chris Wasden
Head
Happify DTx

Matthias Zenker
Senior Vice President & Head, Business Development DTx
GAIA AG

CONFERENCE DAY ONE
DECEMBER 4, 2019

Megan Coder
Executive Director
Digital Therapeutics Alliance

8.50 Chair's Opening Remarks

Robust Clinical Trial Design & Execution

Session Purpose:
The digital therapeutics space is full with confusion on true validation levels of various digital therapeutics, making it more important than ever to ensure trials are designed correctly and robustly. Through interactive discussion, this session tackles the critical steps for clinically evaluated digital therapeutics, highlighting the importance of robust trial methods in representing the evidence-driven route for external approval.

Kai Gait
Senior Global Digital Strategy Director
GSK

9.00 The Future of Digital Therapeutics: The Pharma Perspective
- Digital therapeutics in the future
- How are large organisations looking at new modalities?
- It's beyond innovation, but do organisations understand and are they structured to deliver?

Anil Jina
Chief Medical Officer
Akili

9.30 DTx Clinical Imperatives
- Setting a high bar for clinical validation
- DTx trial design and methodology
- Leveraging digital for real-world data

Olivier Jarry
Chief Commercial Officer & President
DarioHealth

10.00 Improving User Experience to Ensure Rich Data & Reduce Attrition
- The trap of believing "build it (digitally) and they will come"
- Consistent and intense participation of the patient is required to run clinical trials, enact lifestyle changes and deliver outcomes
- Techniques for robust engagement (e.g. attention capture, rewards, gamification)

10.30 Speed Networking

10.45 Morning Refreshments

Joris van Dam
Head, Digital Therapeutics
Novartis

11.00 Running a Pharma Study with a Digital Therapeutic: Our Experiences
- In this talk we'll share our experiences, the good the bad and the ugly
- Running our first proof-of-concept clinical trial at Novartis with the use of a digital therapeutic

11.30 Q&A Session with the Expert Speakers

Key topics to be discussed include:
- Incorporating reliable placebos and blinding to trials, building validity for later stage approval from reimbursement and regulatory systems
- Asking the right questions to find the 'active ingredient': What is truly influencing our results?
- System development for improving user experience for a range of therapeutic modalities

Megan Coder
Executive Director
Digital Therapeutics Alliance

Kai Gait
Senior Global Digital Strategy Director
GSK

Anil Jina
Chief Medical Officer
Akili

Olivier Jarry
Chief Commercial Officer & President
DarioHealth

Joris van Dam
Head, Digital Therapeutics
Novartis

12.30 Networking Lunch

Reimbursement & Commercial Considerations for Informed Development Decisions & Successful Market Access & Adoption

Session Purpose:

As the digital therapeutics space evolves, an understanding of the reimbursement landscape is critical for informed development decisions. This session will tackle the widespread lack of understanding surrounding the payer approach and reimbursement pathways, as well as critical commercial strategies to prepare for streamlined financial success.

Joel Sangerman
Chief Commercial Officer
Click Therapeutics

13.30 Digital Therapeutics: Software as Prescription Medical Treatments

- Hear what healthcare executives need to know and what is being missed
- Learn how prescription digital therapeutics (PDTs) will be integrated in to care protocols
- Understand how reimbursement, medical policies, and drug formularies will change as PDTs enter the market

Adam Kaufman
Co-Founder, Chief Executive Officer & President
Canary Health

14.00 Taking Digital Therapeutics to the Market: Key Considerations in Partnerships & Beyond

- Exploring the strategies for partnership decisions to launch a commercially viable therapeutic
- Taking partner challenges into consideration to ensure mutual benefit and establish a "fair deal"
- Key commercial strategies to build internally, from sales force to scaling, and the effective execution of these in real practice

Chris Hogg
Chief Commercial Officer
Propeller Health

14.30 Overcoming Barriers to Scale in Digital Therapeutics

- The barriers we've overcome so far, and what's next for the industry
- Understanding the current reimbursement path for digital therapeutics
- Overcoming infrastructure issues related to distribution
- Determining the best path to scale: B2C, B2B, B2B2C and everything in between

15.00 Afternoon Refreshments

Matthew Tucker
Director, Strategy & Innovation
Highmark Health

15.30 The Role of Clinical Evidence in Adoption by Payers, Providers & Patients

- Learn how evidence influences customers in different ways and is a critical component of your brand story to drive adoption
- Learn how clinical evidence was used with these groups through real world case studies
- Uncovering the secrets of the medical policy: Understanding the process to validate technologies

Mark Bini
Vice President, Innovation & Member Experience
Express Scripts

16.00 Digital Therapeutics Reimbursement: Charting New Territory

- Understanding payer incentives
- Focusing on value
- Preventing data overload for providers
- Integrating digital and traditional therapies

16.30 Q&A Session with the Expert Speakers

Key topics to be discussed include:

- Understanding evidence requirements of public vs private insurers
- Clarifying the reimbursement categories within the US market, from drug to psychosocial services, and their impact on DTx development and commercialization
- Developing direct to consumer models: Comparing prescribable to over-the-counter routes for consumer accessibility
- Exploring recent guidelines issued by NICE and Germany, and what these mean for international growth

Megan Coder
Executive Director
Digital Therapeutics Alliance

Aaron Gani
Founder & Chief Executive Officer
BehaVR

Joel Sangerman
Chief Commercial Officer
Click Therapeutics

Adam Kaufman
Co-Founder, Chief Executive Officer & President
Canary Health

Mark Bini
Vice President, Innovation & Member Experience
Express Scripts

17.15 End of Day One

CONFERENCE DAY TWO
DECEMBER 5, 2019

Joel Sangerman Chief Commercial Officer **Click Therapeutics**	**8.50**	**Chair's Opening Remarks**

Clinical Integration of Digital Therapeutics to Deliver for Patients Worldwide

Session Purpose:

With digital therapeutics advancing, a key challenge is integrating these into the often convoluted healthcare framework. This discussion-led session addresses everything from the clinical perspective to healthcare workflows to streamline the implementation of these therapeutics across healthcare practices.

Eddie Martucci Founder & Chief Executive Officer **Akili**	**9.00**	**Reimagining Medicine** • Opportunities and expectations for digital therapeutics • Arming patients and doctors with DTx-enabled data • The patient experience of the future
Matthias Zenker Senior Vice President & Head, Business Development DTx **GAIA AG**	**9.30**	**"Are We There Yet?": Lessons Learned from a Decade of Clinical Experience with DTx** • Products, pitfalls and perception: Health care professionals and their understanding of DTx • Outpatient vs inpatient: How DTx can create meaningful impact • Product vs component: DTx as one part of complex interventions • Science does matter: RCTs and their impact on dissemintation in routine care
Shrawan Patel Vice President & Head, Clinical Transformation **Rx.Health**	**10.00**	**Unpicking the Tricky Question of "How To Prescribe a DTx?"** • Discuss what we've learnt on our journey from developing the first enterprise-wide app prescription platform and how that informs our current outlook • Review some of the barriers preventing clinicians from prescribing DTx and how we can overcome these hurdles • If prescribing one DTx was complicated enough, how should we approach prescribing two or more at the same time?
	10.30	**Morning Refreshments & Networking**
Anand Iyer Chief Strategy Officer **WellDoc**	**11.00**	**Digital Therapeutics Engagement Chain: Key Success Factors** • What is the digital therapeutics engagement chain? • Understand how it varies by deployment and operating environment • Determine key performance indicators to prove efficacy

11.30 Q&A Session with the Expert Speakers

Key topics to be discussed include:

- Understanding the current approach of clinicians to digital therapeutics and the current limitations faced in DTx applications
- Discussing the differing privacy and cybersecurity levels across healthcare organizations
- Integrating digital therapeutics to the complex workflows existing in healthcare systems, from clinical dashboards and patient activation to prescription and reimbursement workflows

Joel Sangerman
Chief Commercial Officer
Click Therapeutics

Matthias Zenker
Senior Vice President & Head, Business Development DTx
GAIA AG

Shrawan Patel
Vice President & Head, Clinical Transformation
Rx.Health

Eddie Martucci
Founder & Chief Executive Officer
Akili

Anand Iyer
Chief Strategy Officer
WellDoc

	12.15	**Networking Lunch**

Clarifying the Regulatory Guidelines for Digital Therapeutics

Session Purpose:
Despite placement within the SaMD framework, questions still remain across the regulatory approach for digital therapeutics. This session provides insight into the latest regulatory developments and leading internal strategies to maximise commercial success of digital therapeutics.

Mary Dixon
Chief Executive Officer & Founder
Innovenn

13.15 Regulatory "Must Haves" When Developing Software as a Medical Device (SaMD) That Uses Machine Learning & Artificial Intelligence

- From data to development; creating clinically meaningful software
- Navigating developing US and International regulatory testing requirement and standards
- The importance of Usability, Human Factors and User Interface testing in the development process

Martin Culjat
Senior Vice President, Scientific & Regulatory Affairs
Dthera Sciences

13.30 Regulatory & Reimbursement Implications of FDA Breakthrough Device Designation

- Overview of the FDA Breakthrough Devices program and eligibility criteria
- Discussion on what Breakthrough Device designation might mean for digital therapeutics companies
- Exploring emerging CMS reimbursement opportunities for Breakthrough devices

Safety & Privacy Requirements for Data Collection & Storage

Session Purpose:
Data is at the centre of digital therapeutics, but are we ensuring we respect patient privacy and collect information in accordance to safety laws? This session explores this all-important question to ensure digital therapeutics benefit patients in need while adhering to guidelines to protect patient privacy.

Maria Latushkin
Senior Vice President, Engineering
Omada Health

14.00 Healthcare in the Age of the Consumer: Drawing on the Parallels of Consumer & Healthcare Industries

- Agile methods in product delivery in digital therapeutics
- Tension between traditional consumer approach and clinical prudence
- Creating engaging experiences to improve outcomes

Chris Wasden
Head
Happify DTx

14.30 Creating a Digital Therapeutic Platform to Treat Multiple Therapeutic Areas

- Digital platforms in other industries provide the blueprint for digital therapeutics
- Behavioral health is the meta-condition that is the basis for a digital therapeutic platform
- Comorbid conditions with behavioral health and other diseases enable treating the mind and body

15.00 Afternoon Refreshments

15.30 Roundtable Session: Exploring the Impact of International Guidelines & Laws on DTx Development & Adoption

- HIPPA, CCPA and GDPR: How do these geographical laws impact the national and international use of your digital therapeutic, and how do you develop systems with these in mind?
- How can we develop the frameworks to ensure patients fully understand their given consent?
- Ensuring collected patient information is truly required, and that unnecessary information is safely excluded from databases
- Ensuring safe and effective data exchange between systems for improved interoperability

16.30 End of Day Two & Close of 2nd Clinically Validated DTx Summit 2019

OUR SPONSORS

Innovation Partner

At Innovenn, we are committed to fulfilling the unmet needs of patients and providing tools and insights to doctors and patients to help with disease management. Using AI technology, we can provide a custom patient disease profile and progression analysis which informs current and future care.

Innovenn has spend years developing a unique technology to understand how to optimize the use of clinical and scientific data and then create predictive modeling at an individual patient level. Our approach is to collaborate closely with our client partners through every aspect of the development of a new SaMD solution based on our clients' needs including; identification of unmet needs, delineate business requirements, UX, SaMD development, validation, testing, training and launch.

www.innovenn.com

WHY PARTNER?

Uniting the right partners that, together, will help deliver regulated and clinically evaluated digital therapeutics to patients in need.

The Clinically Validated DTx Summit brings together key stakeholders from pharma, DTx companies, healthcare institutions, wearable developers and technology providers. Partner with us to not only showcase latest developments, but also explore the roadblocks faced in the development, clinical application and commercialization of these innovative therapeutics.

Partner with us to:

Connect with the who's-who of the digital therapeutics space to foster new collaborations

Showcase your expertise to leading organizations through our exhibition space or a position on our expert speaker faculty

Create connections with pioneers to position yourself as the go-to provider in this quickly advancing space

Cement existing relationships through speed networking, one-to-one meetings and multiple industry-wide touch points

GET INVOLVED

Theo Collins
Partnership Director
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Email: sponsor@hansonwade.com

READY TO REGISTER?

3 EASY WAYS TO BOOK

www.clinicallyvalidated-dtx.com/register

Tel: +1 617 455 4188

Email: register@hansonwade.com

1. Execute robust trials for effective validation of your therapeutic
2. Integrate your DTx to routine clinical practice
3. Understand regulatory and reimbursement requirements for streamlined approval
4. Develop key commercial strategies to push through the market

SECURE YOUR PLACE

Package Details	Register & Pay Before 09/06/19	Pre-Event Registration	On The Door
Drug Developer or Digital Therapeutics Company* (Conference Only)	$1,499 **(Save $700)**	$1,899	$2,199
Digital Health Service Provider (Conference Only)	$2,499 **(Save $700)**	$2,899	$3,199

Team Discounts*

- **10% discount – 3 delegates**
- **15% discount – 4 delegates**
- **20% discount – 5 or more delegates**

*Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

Contact: register@hansonwade.com

*Registrants working at academic and healthcare institutions are entitled to a discount on drug developer and DTx company price. Please enquire for further details.

VENUE

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For further information or assistance, please visit www.marriott.com