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SAVE \$900**

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:



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 Interactive, 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



Kai Gait
Senior Global Digital
Strategy Director
GSK



Aaron Gani
Founder & Chief
Executive Officer
BehaVR



Anand Iyer
Chief Strategy
Officer
WellDoc



Olivier Jarry
Chief Commercial
Officer & President
DarioHealth



Anil Jina
Chief Medical Officer
Akili Interactive



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 Interactive



Shrawan Patel
Vice President
& Head, Clinical
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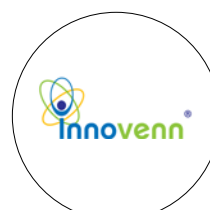
Joris van Dam
Head, Digital
Therapeutics
Novartis



Chris Wasden
Head
Happify DTx



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



**Speaker Confirming
Innovenn**

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 Interactive

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 & Morning Refreshments

Speaker Confirming
Innovenn

11.05 Details Confirming Shortly

Joris van Dam
 Head, Digital
 Therapeutics
Novartis

11.15 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

11.45 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
 Interactive**



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.

Adam Kaufman Co-Founder, Chief Executive Officer & President Canary Health	13.30 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
Joel Sangerman Chief Commercial Officer Click Therapeutics	14.00 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
Matthew Tucker Director, Strategy & Innovation Highmark Health	14.30 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
	15.00 Afternoon Refreshments
Mark Bini Vice President, Innovation & Member Experience Express Scripts	15.30 Digital Therapeutics Reimbursement: Charting New Territory - Understanding payer incentives - Focusing on value - Preventing data overload for providers - Integrating digital and traditional therapies

16.00 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

17.00 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 Interactive

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 dissemination 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
Interactive**



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.

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

Best networking ever! 

Chief Medical Officer, Tilak Healthcare

OUR SPONSORS



Innovation Partner

Innovenn is an innovative skin science company with a unique portfolio of in vitro products and services. Innovenn are at the forefront of reconstructed in vitro skin technologies that are helping to enhance innovative skincare research and development. Our aim is to assist in the discovery and evaluation of skincare products, working with organisations from the cosmetic, personal care, pharmaceutical and medical device sectors, continually developing and providing novel products and services.

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.

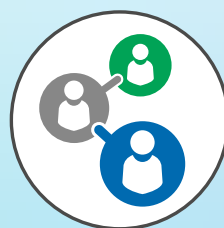
Partner with us to:



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
Tel: +1 508 869 4452
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 08/02/19	Pre-Event Registration	On The Door
Drug Developer or Digital Therapeutics Company* (Conference Only)	\$1,299 (Save \$900)	\$1,899	\$2,199
Digital Health Service Provider (Conference Only)	\$2,299 (Save \$900)	\$2,899	\$3,199

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

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



VENUE

Renaissance Boston Waterfront Hotel

606 Congress Street
Boston, MA 02210

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

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Hanson Wade reserves the right to postpone or cancel an event, to change the location or alter the advertised speakers. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

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