



Defining How Digital Therapeutics are Going to Integrate into Healthcare

Boston, MA | September 24-26, 2019

Conference Day 1, Tuesday September 24th 2019

Workshop 1 - Digital Therapeutics 101: The Fundamentals of the Industry

Digital therapeutics are amongst the hottest areas in healthcare but in this multifaceted industry, there is a clear need for fundamental questions to be answered for those seeking them. Led by pioneers of the industry, this deep-dive workshop will provide newcomers to digital therapeutics the opportunity to be fully clued up on the basics and primed for the main agenda.

Workshop Leaders:

Agenda

9:00am Presentation: What does the Digital Therapeutics Industry Look like Today?

- How has the digital therapeutics industry got to this point in its history?
- What are the current definitions and main sectors involved in digital therapeutic development and adoption?

9:30am Breakout Discussions:

Splitting into smaller working groups, each group will discuss their current views on digital therapeutics, as well as their views on fundamentals of the industry.

- Are we comfortable with the defining characteristics of a digital therapeutic?
- What are the emerging sub-categories of digital therapeutics?
- What are the current routes to market for digital therapeutics?
- In what disease areas are digital therapeutics set to have the biggest impact?
- What remaining questions do we have about digital therapeutics?

10:30am Refreshment Break

11:00am Feedback Discussions:

Representative(s) from each group share the main points from their discussion to the whole group. Additional questions from moderators and other group members will be raised during this collaborative discussion. Summary thoughts will then be shared by the moderator(s) and all participants will leave with the below:

Leave this workshop with:

- A clear understanding of the defining characteristics of a digital therapeutics and the sub-categories emerging
- A deeper understanding of the leading routes to markets and partnership models for digital therapeutic commercialization
- Up-to-date information on where digital therapeutics are already having a significant impact in healthcare
- A stronger appreciation of the crucial questions facing the industry that will be tackled during the rest of the Summit.
- Your questions answered by industry leading experts and your peers

12:00pm End of Workshop

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Workshop 2 - Hands-on with Digital Therapeutics Regulation

Digital health regulation remains uncertain but crucial progress is being made to ensure that safe and effective treatments make it to patients through healthcare systems.

Led by those who are helping construct this regulatory framework, this hands on session will enable participants to have all of their fundamental and advanced questions answered.

Workshop Leaders:

David Amor, Vice President, Quality & Regulatory Affairs, **Pear Therapeutics**

Agenda

1:00pm Presentation: What does the Current Digital Health Regulatory Landscape Look Like?

- What have been the crucial advancements for digital health regulation?
- In relation to Digital Therapeutics, what are we anticipating the next updates in regulation to entail?

1:30pm Breakout Discussions:

Splitting into smaller working groups, each group will discuss the crucial sub-topics of digital health regulation, as they relate to digital therapeutics specifically...

- What are the different regulatory classifications used in and around the digital therapeutics industry?
- What will be the impact of the FDA Pre-Cert Program has had on the outlook for Digital Therapeutics organizations?
- How do we anticipate the advancement of AI and analysis of real time data to impact regulatory guidelines?
- What impact have recent breakthrough device designations had on digital therapeutics?
- What are the alternatives to regulatory approval?

2:30pm Refreshment Break

3:00pm Feedback Discussions:

Representative(s) from each group share the main points from their discussion to the whole group. Additional questions from moderators and other group members will be raised during this collaborative discussion. Summary thoughts will then be shared by the moderator(s) and all participants will leave with the below:

Leave this workshop with:

- A clear understanding of the current digital health regulatory landscape
- A deeper understanding of how regulation is impacting digital therapeutics
- Up-to-date information on what we are anticipating the next series of updates from regulators to look like
- A stronger appreciation for the more emerging topics of regulation, such as AI and real time data analysis
- Takeaway lessons learned that relate to the level of regulation required for your product(s)/work.

4:00pm End of Workshop

Conference Day 1, Tuesday September 24th 2019

4:30pm **Registration**

Registration is open for **all** conference attendees ahead of the networking evening.

DTx Networking

Networking is an integral part of the DTx Series, which is why there is now more time solely dedicated to it. Utilizing a variety of formats, attendees will be able to make dozens of new connections, meet industry leaders and catch-up with old friends. Immerse yourselves in the digital therapeutics community!

5:30pm **Speed Networking**

The goal of this session is to meet with as many people as possible in just 40 minutes. Introduce yourself to each person around your table, swap business cards and plan to meet up later on. A new group of people will be joining you at 5 minute intervals. It's all about the quantity of new connections at this stage!

6:10pm **1-2-1 Meetings**

Use this dedicated meeting time to catch up with old friends and new connections you have just made, or planned to meet up with during the event.

Space will be set aside for more private conversations, as well as more organic networking to ensure that you meet everyone you want.

7:00pm **Networking Drinks**

After an intense couple of hours of networking, unwind with your peers over a drink or two!

Conference Day 2, Wednesday September 25th 2019

8:00am Breakfast & Networking

9:00am **Chair's Opening Remarks & Setting the Scene**

- How has the Digital Therapeutics industry progressed since DTx West 2019?
- What should we expect to have learned by the end of DTx East 2019?

Jeffrey Abraham, Vice President, Market Access & Trade, [Akili Interactive](#)

Digital Therapeutics: Going Beyond the Headlines

9:15am Presentation - **Digital Health Regulation, Pre-Cert Program as they Relate to Digital Therapeutics**

Bakul Patel, Director, Division of Digital Health, [FDA](#)

9:45am Keynote Panel - **What is Keeping you up at Night about Digital Therapeutics?**

As the fundamentals of digital therapeutics are largely agreed upon and key decision-makers become more familiar with the industry, what needs to happen next? Tapping into the minds of the pioneers of the field, go beyond the headlines and find out what are the most pressing opportunities/challenges these leaders are focused on. Hear their thoughts on provocative questions, such as:

- What do we need to get better at as an industry to accelerate the development and adoption of digital therapeutics?
- How do we clear out the noise in the industry and make the how's and the why's of digital therapeutics clear for the buyers?
- As of today, what is working with digital therapeutics and what isn't?
- Is it a danger if the digital therapeutics industry becomes too similar to pharma?
- What's the one main thing you can share with the audience that won't be heard anywhere else?
- What do you hope is achieved by the end of DTx East 2019?

Megan Coder, Executive Director, [Digital Therapeutics Alliance](#)

David Klein, Co-Founder & Chief Executive Officer, [Click Therapeutics](#)

Eddie Martucci, Co-Founder & Chief Executive Officer, [Akili Interactive](#)

Alex Waldron, Chief Strategy Officer, [Pear Therapeutics](#)

10:45am

Morning Refreshments & Networking

As the digital therapeutics industry continues to mature, expand and new stakeholders become involved, there is a crucial need to go deeper into the core questions and focus on the challenges of tomorrow.

The rest of Day 2 will be split into two tracks to enable more dedicated discussions on routes to market and focus exclusively on emerging perspectives.

Attendees will be able to switch between tracks throughout the day.

Track 1

Routes to Market for Digital Therapeutics

Chair: **Jeffrey Abraham**, Vice President, Market Access & Trade, [Akili Interactive](#)

Track 2

Showcases & Crucial Considerations

Chair: **Ed Cox**, Chief Executive Officer, [Dthera Sciences](#)

11:30am Presentation - **How to Partner with Self-Insured Employers**

<ul style="list-style-type: none"> • What are self-insured employers looking for when digital therapeutic companies approach them? • As validated digital interventions become common in self-insured employers, what lessons are being learned by digital therapeutic companies trying to secure partnerships? <p>Dannielle Sherrets, Director, Health Innovations & Special Projects, National Business Group on Health</p>	<p>11:30am Presentation - Forging Hope Against in the Fight Against Alzheimer’s Disease through Digital Therapeutics</p> <ul style="list-style-type: none"> • In light of drug trial fails, are digital therapeutics the only way to successfully manage cognitive health before the onset of Alzheimer’s? • Can non-pharmacological interventions be the missing link between good memory health and cognitive decline? <p>Elli Kaplan, Chief Executive Officer, Neurotrack</p>
<p>11:55am Presentation - Breaking Down Silos: Why Digital Health Solutions Need the Ecosystem to Succeed</p> <ul style="list-style-type: none"> • <i>How best to incorporate an ecosystem approach to your digital therapeutic work</i> • <i>Understand what are the infrastructure challenges facing digital therapeutic companies and the opportunities out there to solve these</i> <p>Speaker to be confirmed, BrightInsight, a Flex Company</p>	<p>11:55am Presentation - Applying Novel Evidence Generation Techniques to Digital Therapeutics Development</p> <ul style="list-style-type: none"> • <i>What solutions are out there to improve data capture from digital therapeutic clinical studies?</i> • <i>How is real world evidence informing clinical studies?</i> <p>Speaker to be confirmed, IQVIA</p>
<p>12:20pm Lunch & Networking</p>	
<p>2:00pm Fireside Chat and Open Q&A - Integration of Digital Therapeutics in Novartis/Sandoz</p> <ul style="list-style-type: none"> • How are Novartis/Sandoz incorporating digital therapeutics into their core business strategy? • How have Novartis/Sandoz integrated digital therapeutics into clinical development? • How are Novartis/Sandoz breaking down the walls internally to advance the development of digital therapeutics? 	<p>2:00pm Panel - What Level of Clinical Evidence is Required for Digital Therapeutics?</p> <ul style="list-style-type: none"> • How are companies recruiting patients for digital therapeutic clinical trials? • How are digital therapeutic clinical trials being structured? • What level of clinical evidence are regulatory authorities looking for?

<p>Andre Heeg, Head of Digital, Sandoz Joris van Dam, Executive Director, Head of Digital Therapeutics, Novartis</p>	<ul style="list-style-type: none"> ● What level of clinical evidence are payers looking for? ● Is Real World Evidence an option when demonstrating the value of digital interventions? <p>Anil Jina, Chief Medical Officer, Akili Interactive Jo Masterson, Chief Product Officer, 2Morrow Inc Acacia Parks, Chief Scientist, Happify Health</p>
<p>2:45pm Panel - Pharma and DTx Partnerships - A Match Made in Heaven?</p> <ul style="list-style-type: none"> ● What are the common factors of a DTx-Pharma partnership starting to look like? ● At what level do pharma “value” the addition of digital therapeutics to their strategies? ● Operationally, how do you actually combine tech with drugs into a unified product? ● How will pharma integrate digital therapeutics into their sales and marketing machines? ● What would early success from the first DTx-Pharma partnerships mean for other pharma? <p>Spencer Jones, Vice President, Global Medical Affairs, Sandoz Bozidar Jovecevic, Vice President, Global Head of Digital Therapeutics, Sanofi</p>	<p>2:45pm Panel - Providers Perspectives: How do Digital Therapeutics need to Adapt to Fit into Healthcare Systems?</p> <ul style="list-style-type: none"> ● How are clinicians and healthcare providers viewing digital therapeutics? ● What are the key questions that providers have when digital therapeutic companies approach them? ● How can digital therapeutics integrate into patient plans? ● What can realistically be adapted in current healthcare systems to increase the adoption of digital therapeutics? ● How should digital therapeutic companies work together to build the infrastructure that will get these products to patients? <p>Yvonne Yu-Feng Chan, Director, Center for Digital Health, Icahn School of Medicine at Mount Sinai Dan Henderson, Primary Care Physician, Massachusetts General Hospital</p>
<p>3:30pm Afternoon Refreshments & Networking</p>	

<p>4:00pm Panel - What Should the Infrastructure Look like to get Digital Therapeutics to Patients?</p> <ul style="list-style-type: none"> • What does the ideal infrastructure for getting digital therapeutics to patients look like? • Outside of self-insured employers, what infrastructure currently exists to get validated digital interventions to patients? • Should digital therapeutic companies be exploring a “digital pharmacy”-type system? • What do digital therapeutic companies need to do to make robust infrastructure a reality? • How are patient advocacy organizations working to get digital interventions to patients? <p>Timothy Aungst, Associate Professor, Pharmacy Practice, MCPHS University Crystal Broj, Chief Technology & Digital Officer, American Association of Diabetes Educators Patricia Simon, Director, Innovation Impact, Yale School of Medicine</p>	<p>4:00pm Presentation - Voice-based Technology - The Next Generation of Digital Medicine?</p> <ul style="list-style-type: none"> • How can voice-based technology improve the mental and physical health of patients? • Understand the results from early proof-of-concept work • How are we planning on integrating novel technologies, such as voice-based, into healthcare? <p>Jim Harper, Co-Founder & Chief Operating Officer, Sonde Health</p>
<p>4:45pm Panel - Digital Therapeutics Commercialization: Lessons Learned from the Front Line</p> <ul style="list-style-type: none"> • What do digital therapeutic companies need to know before making a decision on who to partner with to get to their target market, if they want to partner at all? • What are the key nuances of approaching and working with integrated delivery networks? • How are digital therapeutic companies approaching conversations about being a complementary or combination offering for patients? • Should digital therapeutic companies be thinking about collaborating with each other to reach their target market better? 	<p>4:25pm Panel - What do Digital Therapeutic Companies Need to Demonstrate when Looking to Secure Investment?</p> <ul style="list-style-type: none"> • What are the key things digital therapeutic companies need to prepare before getting in touch with investors? • What is the single biggest concern investors have about digital therapeutics right now? • How is early market consolidation impacting how investors assess companies? • How are mergers and acquisitions set to impact investor perspectives? • How do investors expect to see the digital therapeutic market progress? <p>Pavan Choski, Investment Associate, Arkitect Ventures</p>

<ul style="list-style-type: none"> Is the diversification of business models good for the digital therapeutics industry? <p>Peter Hames, Co-Founder & Chief Executive Officer, Big Health</p> <p>Debra Reisenhel, Founding Chief Executive Officer, Palo Alto Health Sciences</p> <p>Mark Bini, Vice President, New Solutions, Express Scripts</p>	<p>Shaan Gandhi, Principal, Longwood Fund</p> <p>Chihiro Hosoya, BD / VC Head, Rx+ Business Accelerator, Astellas Venture Management</p> <p>Zack Lynch, Managing Partner, JAZZ Venture Partners</p>
<p>5:30pm Drinks Reception</p> <p>After an intense day of learning and networking, catch up with old friends and new connections over a drink.</p>	

<p>Conference Day 3, Thursday September 26th 2019</p>
<p>8:00 Breakfast & Networking</p>
<p>9:00 Chair's Opening Remarks</p> <ul style="list-style-type: none"> Recap of Day 1 – what lessons have been learned already and what discussions stood out? A look ahead at Day 2 – what can we expect to learn today? <p>Adam Kaufman, Chief Executive Officer, Canary Health</p>
<p>9:10 Presentation - 8 Weeks, 4 Consultants, 1 Company: Insights and Results from the DTx East Slingshot</p> <p>Michael Lieberman, PhD, Senior Vice President, Medical Sciences, Klick Consulting</p> <p>Jennifer White, Senior Vice President, Strategic Partnerships, Klick Consulting</p>

The Regulatory & Reimbursement Landscapes of Digital Therapeutics

9:35 Presentation - **Launch Considerations and Preparations Before Approaching a Payer**

- Generally speaking, how are payers currently viewing digital therapeutics?
- What do digital therapeutic companies need to have in place before approaching a payer?

Matthew Tucker, Executive Director, Strategy & Transformation, [Highmark Health](#)

9:50 Panel - **The Reimbursement Landscape for Digital Therapeutics**

As the digital therapeutics industry continues to swell, crucial questions around working with payers and securing coverage are becoming the main focus of the field. Hear how payers are viewing digital therapeutics and the key factors to consider when looking to work with them. Tap into the mind of leading payers and key opinion leaders to hear their thoughts on:

- How should digital therapeutic companies present their results and offerings in an efficient way for payers to evaluate?
- How should digital therapeutic companies showcase how their product will fit into current healthcare plans and workflows?
- What does good look like for evidence requirements when it comes to making a medical policy decision?
- How are payers going to compare digital therapeutics to other interventions?
- What is the one leaving piece of advice payers would share with digital therapeutic companies?

Moderator: **Pierre Leurent**, Chief Executive Officer, [Voluntis](#)

Charlie Gross, Vice President, National, Behavioural Health, [Anthem, Inc.](#)

Sukanya Soderland, Chief Strategy Officer, [Blue Cross Blue Shield Massachusetts](#)

10:35

Morning Refreshments & Networking

Digital Therapeutics Showcase

11:20 Presentation - **How to Build and Scale Digital Therapeutics in Emerging Markets**

- Understand how digital therapeutics are being integrated into the healthcare systems in India and SouthEast Asia
- Recent clinical results from several disease states will be showcased
- What are some of the challenges faced so far, and those to come in the future, for Digital Therapeutics in these markets?

Abhishek Shah, Co-Founder & Chief Executive Officer, [Wellthy Therapeutics](#)

11:45 Presentation - **The Role of Digital Therapeutics in the Consumerization of Health**

- Understand how digital therapeutics are being integrated into the Israeli healthcare system
- Recent clinical results will be showcased
- Discussion will focus on how Dario Health is planning to embed further into Israel

Erez Raphael, Chief Executive Officer, [Dario Health](#)

12:10 Presentation - **Presentation by Ieso Digital Health**

Andy Blackwell, Chief Scientific Officer, [Ieso Digital Health](#)

12:35 **Lunch & Networking**

2:00 Panel - **What do we do Great and What do we Need to Get Better at as an Industry?**

Digital therapeutics are rapidly accelerating into the healthcare mainstream but there are plenty of opportunities to continue to “professionalize” this industry. Understand how industry leaders are viewing the future of the field and what opportunities there are to work together as a community to further accelerate this progression. Hear their closing thoughts on:

- What do we need to get better at as an industry to accelerate the development and adoption of digital therapeutics?
- What partnership opportunities can we cultivate to help “professionalise” the industry?
- How will market consolidation impact us as an industry?
- What have been your key takeaways from the last three days that fill you with optimism for the future?
- What are you expecting the discussion to be focusing on at DTx West 2020?

Mette Dhyrberg, Founder & Chief Executive Officer, [Mymee](#)

Owen McCarthy, Co-Founder & President, [MedRhythms](#)

Pablo Pantaleoni, Vice President & General Manager, **Headspace**

2:45 Chair's Summary

- What have been the key lessons learned from the DTx East 2019?
- What do we want to be discussing at DTx West 2020?

Adam Kaufman, Chief Executive Officer, **Canary Health**

2:50 Close of DTx East 2019