



# DTx

## 3 r d ANNUAL | WEST

Conference Day 3, Thursday February 20th, 2020

### Workshop 1 - The Business of Digital Therapeutics

The digital therapeutics industry has proved to be broad and multifaceted. This had led to numerous approaches in building a DTx business, validating the product and taking it to market. This workshop, led by leaders within the industry, will explore the various business models, routes to market and discuss if a digital therapeutics company can truly be a dual entity business.

#### Workshop Leaders:

**Debra Reisenthel**, Founding CEO, **Palo Alto Health Sciences**

**Everett Crosland**, VP Commercial, **AppliedVR**

**Jonas Duss**, US CEO, **Kaia Health**

**Antoun Nabhan**, VP, Corporate Development, **Pear Therapeutics**

#### Agenda

9:00am Presentation: An Inside Look at the Business of Digital Therapeutics

- A brief overview of the various business models adopted by digital therapeutic companies
- An insight into the various routes to market
- Can DTx companies exist with both FDA and Non-FDA regulated therapeutics or do you have to “pick a side”

9:30am Breakout Discussions

Splitting into smaller groups, you will discuss the intricacies of the business of digital therapeutics and hear views on how best to successfully run a business in the DTx industry.

- What are the current business models being used within the industry and which are demonstrating the most success?
- How do some business models favour certain types of digital therapeutic over others?
- Can a digital therapeutic company successfully develop and market both FDA & non-FDA regulated digital therapeutics?
- What are the route to market opportunities available to the DTx industry?

10:30am Refreshment Break

11:00am Feedback Session

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 deeper understanding of the various business models demonstrated by digital therapeutic companies
- Up-to-date information on business models of varying successes in the current industry
- A clear understanding of if it's possible to successfully a dual entity business or if companies truly have to "pick a side"
- A clear understanding of current routes to market and their intricacies
- Your questions answered by industry leaders and your peers

12:00pm **End of Workshop**

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**Conference Day 3, Thursday February 20th, 2020**

**Workshop 2 - Clinical Trials - Separating the Digital from the Traditional**

Digital therapeutic clinical trials provide the opportunity to validate and gain regulatory approval for the therapeutic. While the FDA's requirement for placebo comparison is omnipresent, the nature of a "placebo" in a DTx content is not yet well defined. This workshop will dive into the trials of DTx and focus on how best to move forward.

**Workshop Leaders:**

**Acacia Parks**, Chief Scientist, **Happify Health**

**Jenna Carl**, VP of Clinical Development & Medical Affairs, **Big Health**

**Derek Richards**, Chief Science Officer, **SilverCloud Health**

**Agenda**

1:00pm Presentation: An Introduction into Digital Therapeutic Clinical Trials

- How do digital therapeutic clinical trials differ from traditional drug trials?
- An introduction of comparison groups and digital trial design

1:20pm Panel Discussion:

Led by leaders in the industry all with in-depth experience of DTx clinical trials, this panel will dive into clinical trial considerations when designing trials for digital therapeutics

- What are the requirements when designing digital therapeutic clinical trials?
- What does the FDA require from clinical trials for them to be acceptable?
- What does a SHAM/placebo look like in the DTx clinical trial?
- Should DTx companies and the FDA be working together to produce the right SHAM for each trial?

2:10pm Free write

This is your chance to finalise your notes and prepare questions for the workshop leaders and your peers for after the break!

2:15pm Refreshment Break

2:45pm Breakout Discussions

Splitting into smaller groups, each group will discuss their own views on digital therapeutic clinical trials and work on how best to move forward in this space.

- What are the current issues we face when designing clinical trials for digital therapeutics?
- What considerations should you have in mind when designing SHAM trials?
- What are the current guidelines for DTx clinical trials outlined by the FDA?
- How can we work with governing bodies to ensure DTx clinical trials are both suitable and feasible?
- What does a suitable and usable SHAM trial look like?

3:20 Feedback Discussions

Representatives from each group will share their main points from their discussion with the whole workshop.

Workshop leaders and members from all groups will facilitate the discussion with their own thoughts and questions in this collaborative session.

Summary thoughts will be shared by workshop leaders and all participants will leave with the below:

**Leave this workshop with:**

- A clear understanding of the clinical trial landscape for digital therapeutics
- A deeper understanding on how best to build a SHAM/placebo for a DTx clinical trial
- An understanding on current FDA clinical trial guidelines in the space
- A greater understanding of important considerations to keep in mind when designing a DTx clinical trial
- Your questions answered by industry leading experts and your peers

4:00pm **End of Workshop**

**Conference Day 1, Tuesday February 18th, 2020**

8:00am Breakfast and Networking

9:00am **Chairs Opening Remarks and Setting the Scene**

**Adam Kaufman**, President & CEO, **Canary Health**

### Digital Therapeutics - The End Game

9:10am Fireside Chat: **How can Health Plan Partnerships be an Accelerant to DTx Innovation, Commercialisation and Patient Adoption?**

- How did the partnership come to fruition? - Why them and why now?
- What have Yes Health and Better Therapeutics learnt from their partnership with Blue Shield and vice versa?
- How can healthplans aid with patients adoption, adherence and product scalability?
- What are some of the success stories of DTx companies partnerships with Blue Shield?
- What are the challenges payers face when partnering with DTx companies and vice versa?
- How can we be the catalyst to disrupt the current system for the new generation of healthcare?

**Bryce Williams**, VP, Lifestyle Medicine, **Blue Shield of California**

**Alex Petrov**, Founder & CEO, **Yes Health**

**Kevin Appelbaum**, Co-Founder & CEO, **Better Therapeutics**

9:50am Presentation: **Noom, Healthier Lives Through Behavior Change**

**Saeju Jeong**, Co-Founder & CEO, **Noom**

10:15am Panel Discussion - **How can we Achieve Replicable Digital Therapeutics Reimbursement?**

With a number of digital therapeutics now firmly established within the industry, the question on everyone's mind is achieving reliable and replicable reimbursement. This panel, led by experts in the industry, will deep-dive into how the DTx industry can achieve the desired endgame of reimbursement.

- 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 an industry, what steps can we take to achieve more coverage from payers and buyers?
- A number of DTx companies have successfully achieved reimbursement, how can we now scale this and achieve replicable and reliable reimbursement?

Moderated by **Brent Vaughan**, CEO, **Cognoa**

**Alex Waldron**, Chief Strategy Officer, **Pear Therapeutics**

**Mette Dyheberg**, Founder & CEO, **Mymee Inc**

**Peter Hames**, Co-Founder & CEO, **Big Health**  
**Yasodhara Paruchura**, VP, Value and Access, **Happify Health**

**11:00am Morning Refreshments and Networking**

DTx West will now split into two tracks. Attendees are welcome to attend either track 1 or track 2 and swap between during the course of the day

<p style="text-align: center;"><b>Track 1 Evidence</b></p> <p style="text-align: center;"><b>Defining Evidence Standards for Digital Therapeutics</b></p> <p>Chair: <b>Acacia Parks</b>, Chief Scientist, <b>Happify Health</b></p>	<p style="text-align: center;"><b>Track 2 Value</b></p> <p style="text-align: center;"><b>Building the Value Proposition for Digital Therapeutics</b></p> <p>Chair: <b>Adam Kaufman</b>, President &amp; CEO, <b>Canary Health</b></p>
<p>11:40am Presentation: <b>Is there a Bar of Validation for Digital Therapeutics?</b></p> <ul style="list-style-type: none"> <li>● An in-depth look as to if there is a defined bar of validation set for digital therapeutic clinical trials</li> <li>● Do FDA and non-FDA regulated Digital therapeutics require different levels of validation or should it be uniform?</li> <li>● A look at the current requirements for DTx clinical trials to be considered successful.</li> </ul> <p><b>Acacia Parks</b>, Chief Scientist, <b>Happify Health</b></p>	<p>11:40am Presentation: <b>Understanding the Commercial Landscape of Digital Therapeutics</b></p> <ul style="list-style-type: none"> <li>● An deep-dive into the current commercial landscape for digital therapeutics</li> <li>● An insight into how different business models are more suited to different DTx businesses</li> <li>● A look at the routes to market currently being utilized by digital therapeutics</li> </ul> <p><b>Andy Molnar</b>, Senior Director, Market Access, <b>Cognoa</b></p>
<p>12:05pm Presentation: <b>Digital Therapeutics + Virtual Clinical Trials: An Ideal Match</b></p> <ul style="list-style-type: none"> <li>● How virtual clinical trials bring clinical research directly to patients, delivering more rapid patient enrollment, higher retention, better data quality and overall faster cycle times</li> <li>● Lessons learned from delivering 100% virtual studies evaluating the safety and efficacy of digital therapeutics to achieve key endpoints.</li> <li>● How early planning can fuel greater</li> </ul>	<p>12:05pm Presentation: <b>Realizing Value from Digital in the Healthcare Environment</b></p> <ul style="list-style-type: none"> <li>● What is my commercial model? What is my pricing model? How are payers thinking about my disease? Who pays today? Will I get coverage?</li> <li>● How does a doctor’s prescription turn into a patient’s download and use?</li> <li>● What answers do I need now vs. later?</li> </ul> <p><b>Jonathan Hodgson</b>, Senior Principal, <b>Promidian</b>, an <b>EVERSANA</b> company</p>

<p>patient insights, stronger patient engagement, and support a trial sponsor's long-term success.</p> <p><b>Josh Rose</b>, VP and Global Head, <b>IQVIA R&amp;D Solutions Strategy, IQVIA Virtual Trials</b></p>	
<p>12:30pm Panel Discussion: <b>How does Lack of Clarity in Setting the Bar for Evidence effect Value?</b></p> <ul style="list-style-type: none"> <li>Does not having a standardized bar of validation for clinical evidence affect the value of the digital therapeutic?</li> <li>Does high quality evidence causate to high value or are there other factors involved?</li> <li>When looking to partner with digital therapeutic companies, does the lack of standardized bar of validation affect the perceived value of a DTx?</li> </ul> <p><b>Veena Rao</b>, Senior Director, Search &amp; Evaluation, Device Delivery, Connected Systems, &amp; Digital Health, <b>Eli Lilly</b>  <b>Jonas Duss</b>, US CEO, <b>Kaia Health</b>  <b>Jo Masterson</b>, Co-Founder, CPO &amp; COO, <b>2morrow Inc.</b></p>	<p>12:30pm Panel Discussion: <b>Building the Bridge between Evidence and Value</b></p> <ul style="list-style-type: none"> <li>What is the process of determining value from clinical evidence?</li> <li>How can you put a price tag on validated clinical evidence?</li> <li>Are digital therapeutics companies in the best position to put a value on clinical evidence or is this the role of the payers?</li> <li>Does good evidence translate directly into value or are there other factors involved?</li> </ul> <p><b>Jeff Abraham</b>, VP of Market Access &amp; Trade, <b>Akili Interactive</b>  <b>Andy Molnar</b>, Senior Director, Market Access, <b>Cognoa</b>  <b>Kate Rosenbluth</b>, Founder &amp; CEO, <b>Cala Health</b></p>
<p><b>1:10pm Lunch and Networking</b></p>	
<p><b>Methods of Evidence Generation and Translation</b></p>	<p><b>Translating the Value Proposition of Digital Therapeutics</b></p>

<p>2:00pm Presentation: <b>The In's and Out's of Randomized Controlled Trials for DTx Clinical Validation</b></p> <ul style="list-style-type: none"> <li>• A look into current RCT protocol for digital therapeutic clinical trials</li> <li>• Deep-dive into requirements for RCT's to be considered suitable for FDA regulation</li> <li>• What does a placebo look like in a DTx clinical trial?</li> </ul> <p><b>Derek Richards</b>, Chief Scientific Officer, <b>SilverCloud Health</b></p>	<p>2:00pm Presentation: <b>Pharma Partnerships in Action</b></p> <ul style="list-style-type: none"> <li>• A look at Happify's recent partnership with Sanofi</li> <li>• Looking back, how did Happify and Sanofi begin discussions for partnering</li> <li>• Looking forward, how are Happify and Sanofi working together to develop Happify's prescription digital therapeutic for MS?</li> </ul> <p><b>Chris Wasden</b>, Head of HappifyDTx, <b>Happify Health</b></p>
<p>2:25pm <b>Presentation: Clinical Trials for Digital Therapeutics: Evolution, Evidence, and Execution</b></p> <p><b>Wayne Bowden</b>, Senior Director, Program Development, <b>Biorasi</b></p>	<p>2:25pm Presentation: <b>Digital Therapeutics: Creating Value in Autoimmune Disease</b></p> <p><b>Mette Dyheberg</b>, Founder &amp; CEO, <b>Mymee Inc</b>  <b>Melinda Decker</b>, Principal, <b>Digital Health Advisor</b></p>
<p>2:50pm Panel Discussion: <b>Understanding the Fundamentals of Demonstrating Clinical Efficacy</b></p> <ul style="list-style-type: none"> <li>• What are the current methods of demonstrating clinical efficacy in digital therapeutics?</li> <li>• A look at RCT's, RWE studies and HEOR studies for evidence generation</li> <li>• Is there a best practice for evidence generation for digital therapeutics?</li> </ul> <p>Moderated by <b>Sharief Taraman</b>, CMO, <b>Cognoa</b>  <b>Debra Reisenhel</b>, Founding CEO, <b>Palo Alto Health Sciences</b>  <b>Jenna Carl</b>, VP of Clinical Development &amp; Medical Affairs, <b>Big Health</b>  <b>Megan Oser</b>, VP of Clinical Innovation, <b>Mahana Therapeutics</b>  <b>Marilen Abbago</b>, Senior Virtual Trials Project Leader, <b>IQVIA</b></p>	<p>2:25pm Presentation: <b>Implementing Digital Therapeutics into the Core Efforts alongside Traditional Drugs at Genentech</b></p> <ul style="list-style-type: none"> <li>• How are Genentech incorporating digital therapeutics into their core business strategy?</li> <li>• How are Genentech breaking down the walls internally to advance the development of digital therapeutics?</li> <li>• How have Genentech integrated digital therapeutics into clinical development?</li> </ul> <p><b>Mikael Eliasson</b>, Global Head of Innovation, Neuroscience Product Development, <b>Genentech</b></p>

3:30pm

**Afternoon Refreshments and Networking**

**Implementation of Digital Therapeutics**

4:05pm Presentation: **Operational and Tactical Considerations to Ensure the Success of your Commercial Strategy**

- An in-depth discussion on what to consider when constructing a DTx commercial strategy
- Understanding the true timelines of commercializing DTx
- What is best practice when interacting with payers, providers and patients?

**Dale Houston**, Strategic Account Executive, Payer Contracting, **EnvoyHealth**

**Natasha Mayfield**, Vice President, **EnvoyHealth**

4:30pm Panel Discussion: **What's Going to Stop Digital Therapeutics from Breaking Big?**

As the digital therapeutics industry enters into the next phase of its lifecycle, key questions are emerging on what will be the next set of roadblocks we need to overcome. Tap into the mind of key industry leaders to hear their thoughts on the following:

- What do external stakeholders think digital therapeutic companies need to do to break big?
- Who are going to be the key partners that will help digital therapeutic achieve long-term scalable success?
- 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?
- Will we be able to give the industry enough time to implement and grow?
- How do we frame what success looks like as an industry?

Moderated by **Ed Cox**, CEO, **Dthera Sciences**

**Pierre Laurent**, Founder & CEO, **Voluntis**

**Paul Schultz**, Senior Director, Commercial Development, **BrightInsight**

**Matt Omernick**, Co-Founder & Chief Creative Officer, **Akili Interactive**

**Megan Coder**, Executive Director, **Digital Therapeutics Alliance**

5:20pm **Chairs Closing Remarks**

**Adam Kaufman**, President & CEO, **Canary Health**

5:30pm **Drinks Reception**

**Sponsored by Virgin Pulse**

6:30pm **Close of DTx West Day 1**

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**Conference Day 2, Wednesday February 19th, 2020**

8:00am Breakfast and Networking

9:00am Chair Opening Remarks

- 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?

**Matthew Tucker**, Head of Vital Program, Chief Marketing Officer, **Highmark Health & NightWare**

9:10am Fireside Chat: **The First Acquisition of Digital Therapeutics**

- How and why did ResMed make the decision to acquire Propeller Health?
- Moving forward, how will this acquisition benefit Propeller Health's digital therapeutic program?
- What has changed internally for Propeller Health after the acquisition?

**Chris Hogg**, Chief Commercial Officer, **Propeller Health**

**Timothy Kern**, Vice President, Strategy & Business Development, **ResMed**

**Scaling Digital Therapeutics for World Domination**

9:50am Panel Discussion: **Scaling Digital Therapeutics for Sustainable Success**

Digital therapeutics are accelerating into the healthcare mainstream but crucial challenges remain in scaling their development, adoption and reimbursement for sustainable success. This panel will showcase insights from commercial leaders at the frontline of the industry. Hear their thoughts on:

- How are digital therapeutics companies working to scale their products?
- How are we thinking about the globalisation of digital therapeutics?
- What partners are needed to scale for sustainable success?
- What lessons can we learn from other industries who have achieved scalable success with similar business models?
- How should digital therapeutics companies be working together to develop best practices that we can all benefit from?

Moderated by **Ross Muken**, Chief Financial Officer, **Click Therapeutics**  
**Elli Kaplan**, Co-Founder & CEO, **Neurotrack**  
**Chris Hogg**, Chief Commercial Officer, **Propeller Health**  
**Kevin McRaith**, President and CEO, **Welldoc**

**10:30am Morning Refreshments and Networking: Sponsored by Yes Health**

**11:10am Panel Discussion: What do Investors Really Think of Digital Therapeutics?**

As the digital therapeutics enters the next phase in its lifecycle, the sentiment from the investor community is changing. Tap into the mind of leading investors to understand how digital therapeutic companies and their partners should alter their approaches.

- How has the investor industry changed its view on digital therapeutics since the first DTx West in February 2018?
- How much of the investment from VC's and Pharma are truly committed to digital therapeutics?
- As exits start to happen in this space, how is this influencing the investor perspective?
- How are investors preparing to help scale digital therapeutics companies?
- How can investors work with digital therapeutics companies and their partners to help them through this next phase of the industry's life cycle?

Moderated by **Elan Tye**, Principal, **JAZZ Venture Partners**  
**Liz Rockett**, Director, **Kaiser Permanente Ventures**  
**Vas Bailey**, Partner, **Artis Ventures**  
**Ruchita Sinha**, Venture Partner, **AV8 Ventures**  
**David Stevenson**, Managing Director, **Merck Global Health Innovation Fund**

### **Digital Therapeutics in Action**

**11:50am Presentation: Prescription Digital Therapeutics for Neuro-Muscular Conditions**

- How are digital therapeutics being developed to treat neuro-muscular conditions?
- How can digital therapeutics deliver improved outcomes in this disease state compared to traditional pharmaceuticals?
- A look at clinical results and plans for the future

**Siva Nadarajah**, Co-Founder & President, **JOGO Health**

**12:15pm Presentation: Creating synergy with DTx: How DTx benefits healthcare system stakeholders**

- What are the differences between developing digital therapeutics in Japan compared to the U.S.?

- How are CureApp translating their work from the Japanese market to the U.S.?
- Discussion will also focus around early clinical results

**Kohta Satake**, Co-Founder & CEO, **CureApp**

12:40pm Presentation: **In-house Production of Traditional and Digital Therapeutics for a Combination Approach**

- Discussion will focus on how Closed Loop Medicine are building digital therapeutics alongside traditional pharmaceuticals
- What are the benefits that this approach is expected to yield?
- A look at early results from this combination approach

**David Cox**, Co-Founder & Chief Digital Officer, **Closed Loop Medicine**

**1:05pm Lunch and Networking**

1:45pm Panel Discussion: **Lessons Learned from the Front Line of Digital Healthcare**

As digital therapeutics integrate into healthcare, crucial lessons are being learnt at this intersection. Hear from those on the front-line dealing with patients during this multi-stakeholder panel. Wrapping-up the discussion at DTx West 2020 as we focus on:

- How are we working with patients to improve the adoption of digital therapeutics?
- How do digital therapeutics companies need to think differently to improve adoption?
- What lessons can we learn from other areas of digital health that are improving outcomes for patients?
- What can we do as a collective industry to better translate the value of digital therapeutics to key stakeholders?
- What do we want the patient landscape for digital therapeutics to look like at DTx East 2020?

**Trina Histon**, Senior Principal Consultant, Prevention, Wellness & Digital Health, **Kaiser Permanente**

**Ben Rosner**, Assistant Professor, **UCSF**

**Rajan Merchant**, Allergy, Asthma, and Clinical Immunology Specialist, **Woodland Clinic Medical Group**

**Kara Tibbe**, Training & Development Specialist, **Spectrum Health**

**Pablo Pantaleoni**, VP and General Manager, **Headspace Health**

2:20pm Chairs Closing Remarks

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

**Matthew Tucker**, Head of Vital Program, Chief Marketing Officer, **Highmark Health & NightWare**

2:30pm Close of DTx West Day 2