

Defining How to Achieve Commercial and Patient Success with Digital Therapeutics

San Mateo, CA | February 26th-28th, 2019

Workshop 1, Tuesday February 26th 2019

Workshop 1: Digital Therapeutics 101

As the digital therapeutics industry continues to swell with its growing pioneers, the next wave of innovators and new sectors entering into the space, there is a need for newcomers to have their fundamental questions answered. Led by pioneers of the industry, this deep-dive workshop will provide newcomers to the digital therapeutics industry the opportunity to be fully clued up on the basics and primed for the main conference.

Workshop Leaders:

Jeffrey Abraham, Vice President, Market Access & Trade, **Akili Interactive Anil Jina**, Senior Vice President, Head of Medical Affairs, **Akili Interactive**

Agenda:

9:00 Presentation: What is the Current State of Play with the Digital Therapeutics Industry?

- 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?

9:30 Breakout Discussions:

Splitting into smaller working groups, each group will discuss their current views on digital therapeutics as a concept and their views on the different facets of the industry.

- Are we comfortable with the definition of a digital therapeutic?

- Generally speaking, how do payers, pharma and regulatory authorities view digital therapeutics?
- What lessons can we draw on from working with other related industries?
- What are our thoughts on the other similar digital medicine approaches out there?
- What remaining questions do we have about digital therapeutics?

10:30 Refreshment Break

11:00 Feedback Discussions:

Representative(s) from each group share the main points from their discussion to the whole group. Additional questions form 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:

- Fundamental questions answered around what a digital therapeutic is being defined as compared to other digital interventions
- A deeper understanding of the current payer and provider perspectives on digital therapeutics and how these are looking to be advanced
- Up-to-date information on the different ways pharma are involved in the industry
- A fundamental understanding of the current regulatory pathways in and around the industry
- A stronger appreciation of the crucial questions facing the industry that will be tackled during the rest of the Summit.

12:00 End of Workshop

Workshop 2, Tuesday February 26th 2019

Workshop 2: Pharma and Digital Therapeutics

As pharma continue to partner and invest into digital therapeutics, there remains uncertainty around the short-term and long-term "role" of pharma in the industry. Led by DTx experts from different sectors, this workshop will focus on the things pharma need to know about digital therapeutics and answer discuss how the industry going to evolve for pharma..

Workshop Leaders:

James Musick, Vice President & Head, Neurology Patient Technology, UCB Chris Wasden, Head of Pharma, Happify Health

Agenda:

1:00 Presentation: What are the Current Sentiments from Pharma Towards Digital Therapeutics?

- Why are certain pharma going all in on digital therapeutics?
- What is holding back other pharma who are yet to make a play in the space?

1:30 Breakout Discussions:

Splitting into smaller working groups, each group will discuss their own thoughts and pharma's current thoughts on digital therapeutics and what it is going to take to make DTx-pharma partnerships successful.

- What are "Digital Therapeutic" in the context of pharma?
- What is our understanding of the expectations from different types of DTx-pharma partnerships?
- How do digital therapeutics fit into the short-term and long-term goals of pharma?
- Are pharma more excited about the therapeutic entity or the data produced by digital therapeutics?
- How should pharma adapt their mindsets to maximize the impact of their work with digital therapeutics?
- How do digital therapeutic companies needs to adapt to maximize the impact of their work with pharma?

2:30 Refreshment Break

3:00 Feedback Discussions:

Representative(s) from each group share the main points from their discussion to the whole group. Additional questions form 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:

- Clear understanding of what a digital therapeutic is as it relates to pharma
- Deeper understanding of the current ways pharma are partnering with digital therapeutics companies
- Full clarification on the expectations pharma have when in a working partnership with digital therapeutic companies compared to purely investing in them
- Discussion points around how pharma currently view digital therapeutics in their short-term and long-term strategies
- Understanding around how different departments in pharma will impact their work in this industry and where a change of mindset is needed
- An understanding of why some pharma are still reluctant to partner with digital therapeutic companies

4:00 End of Workshop

Conference Day 1, Wednesday February 27th 2019 8:00 Registration, Breakfast & Networking

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

- How has the industry progressed since DTx East 2018?
- What should we expect to have learnt by the end of DTx West 2019?

Joel Sangerman, Chief Commercial Officer, Click Therapeutics

Digital Therapeutics: Setting-up for Commercial Success

9:10 Keynote - Lessons Learnt from the Frontline of Digital Therapeutics

- A look at the journey from approval, through launch and post-launch of a digital therapeutic
- What have been the commercial lessons learnt so far?
- Discussion will focus around the socioeconomic impact of this digital therapeutic product

Anand Iyer, Chief Strategy Officer, WellDoc

9:35 Panel - What is it Going take for Digital Therapeutics to Succeed Commercially?

As digital therapeutics continue to receive more interest, the time has come for the critical commercial discussions that will define the future of the industry. Hear from the trailblazers and key opinion leaders as to what they feel needs to happen inside and outside of digital therapeutic companies to translate the promise into a reality for healthcare professionals and patients. Tap into the minds of these leaders by hearing their thoughts on:

- How much will the success of regulatory approved prescription digital therapeutics shape this industry?
- How will the market consolidation of the digital therapeutics industry impact commercial viability?
- As it stands today, what more do digital therapeutic companies need to do to adapt to the current U.S. healthcare system?
- How are companies looking to operationally "sell" digital therapeutics?
- What will be the moment when we know that digital therapeutics have "succeeded" commercially?
- Are digital therapeutic companies selling the whole solution or just part of a larger package for patients?
- How do we plan for the influence that real-time information form digital therapeutics will have on strategy?

Anand Iyer, Chief Strategy Officer, WellDoc
Eddie Martucci, Chief Executive Officer, Akili Interactive
Brent Vaughan, Chief Executive Officer, Cognoa
Alex Waldron, Chief Commercial Officer, Pear Therapeutics
David Lee, Partner, Simon Kucher & Partners

10:20 Morning Refreshments & Networking

11:00 Under the Microscope: Crucial DTx Questions:

These small group discussions provide a unique opportunity to get into the key detail of the challenges and opportunities of crucial questions facing digital therapeutics. Each session has been curated to bring expert moderators together in order for attendees to find questions in a peer-to-peer format. Attendees will be able to attend 3 roundtables, which are 30 minutes each. Get ready for plenty of takeaways in this 90 minute session! Roundtable 1) How do you Transition from Being a Digital Health Company to a Digital Therapeutics Company? Roundtable 2) What Partnership Models are Companies Adopting to Accelerate Development and Commercialization? Giangiacomo Rocco di Torrepadula, Chief Executive Officer & Co-Founder, AMICOMED Roundtable 3) How are Patient Engagement Strategies Being Applied to Digital Therapeutics? Roundtable 4) Working with a Payer - From Medical Policy to Commercialization Debra Reisenthel, President & Chief Executive Officer, Palo Alto Health Sciences Matthew Tucker, Executive Director, Marketing Strategy, Highmark Health Roundtable 5) How do you Develop and Leverage Evidence to Drive Digital Therapeutic Adoption and Use? Roundtable 6) What do Digital Therapeutic Companies need to Display to Investors to Secure Funding? Sasha Said, Vice President, Leerink Transformation Partners 12:30 **Long-Table Lunch & Networking Building for Long-Term Success and Scalability** 1:45 Presentation - The Evolution of Digital Therapeutics Commercialization and Scalability Sean Duffy, Co-Founder & Chief Executive Officer, Omada Health 2:10 Presentation - From Theory to Impact: Lessons Learned from Scaling Digital Medicine in the UK & US

Peter Hames, Co-Founder & Chief Executive Officer, Big Health

2:35 Presentation - Digital Therapeutics Commercialization – What You Need to Know to Get Patients Access to Your DTx

- Understanding the dynamics of insurance coverage, coding and payment and how it can impact patient access
- Patient support needs and how to meet those needs in the digital age
- Lessons learned from traditional commercialization support services and how they apply to DTx

Derek Cothran, Senior Vice President, Client Strategy and Development, EnvoyHealth

3:00 Panel - Why are Companies Now Starting to Pivot Toward Digital Therapeutics?

As more companies pivot towards a "digital therapeutic" approach, there is a need for the industry to understand why this is happening now. In this exclusive session, hear from those who are pivoting towards prescription digital therapeutics and those who are achieving success through different business models. Discussion will focus on:

- How have the key developments with digital therapeutics over the last year changed our thinking?
- If you have great results and are financially successful, should you even consider pivoting?
- What are the economic factors to consider when pivoting?
- How do you translate your current data and outcomes to the regulators?
- What have been the lessons learnt so far from those who are currently altering their business model?

Moderator: Adam Kaufman, President & Chief Executive Officer, Canary Health

Megan Jones-Bell, Chief Scientific Officer, Headspace

Ed Cox, Chief Executive Officer, Dthera Sciences

David Stevenson, Managing Director, Merck Global Health Innovation Fund

3:45

Afternoon Refreshments & Networking

4:15 Presentation - Scalable Digital Tools for Detecting and Training Clinical Inattention Early in Life

- Prevalence of attention deficits is estimated to be 130 million children worldwide
- Early detection and personalised training is key to optimising healthy childhood learning
- The development of novel detection and training tools designed to capture inattention in the early school years introducing TALI Training and TALI Detect

Kim Cornish, Director, Monash Institute of Cognitive and Clinical Neurosciences, Monash University

Adoption and Implementation

4:30 Panel - The In's and Out's of the Regulatory Approval Pathways

As more and more digital health companies seek approval for their products, there is a clear need to understand the current and likely future regulatory landscapes. Hear from those influencing the digital health policy's as the FDA and international bodies continue to update their criteria. Use this session to pose questions to this panel of regulatory experts, such as:

- What are the latest updates from the FDA Pre-Cert Program for Digital Health and prescription Digital Therapeutics in particular?
- 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?

Moderator: David Amor, Vice President, Quality & Regulatory Affairs, Pear Therapeutics

Scott Kellogg, Senior Vice President, Medical Devices, Akili Interactive

Taylor Mahan-Rudolph, Director, Quality & Regulatory, Propeller Health

Austin Speier, Chief Strategy Officer, Click Therapeutics

Chin-Wei Soo, Global Regulatory Head, Combination Products and Devices, Genentech

5:10 Panel - How do Digital Therapeutics need to Adapt to The Healthcare System to be Routinely Prescribed?

As digital therapeutics start to secure regulatory approval and launch, questions are constantly being asked as to how to increase their adoption. Hear from those on the frontline of healthcare, as well as industry leaders, as to how they are looking to increase digital therapeutic implementation. Pose questions to this multi-stakeholder panel, such as:

- Broadly speaking, what are the current trends from physicians and HCP's when it comes to digital health?
- What should digital therapeutic companies be doing to engage and educate prescribers?
- What can be learnt from how patients seek treatments and engage in the 21st century?
- At the ecosystem level, what infrastructure needs to be developed to get digital health to patients at scale?
- How have digital therapeutic companies changed their approaches over the last year when it comes to engaging with physicians?

Moderator: **Sharief Taraman**, Chief Medical Officer, **Cognoa**, Chief of Neurology, **Children's Hospital of Orange County**

Rosemary Ku, Urgent Care Physician, Kaiser Permanente, Founder, Executive Director, Cure Chronic Disease Stephanie Tilenius, Chief Executive Officer & Founder, Vida Health Veera Anantha, Founder, CTO & President, The Learning Corp

5:50 Drinks Reception

After an intense day of learning and discussions, let your hair down with your peers.

Conference Day 2, Thursday February 28th 2019

8:00 Breakfast & Networking

9:00 Chair's Opening Remarks

- Recap of Day 1 what lessons have been learnt already and what discussions stood out?
- A look ahead at Day 2 what can we expect to learn today?

Mette Dyhrberg, Chief Executive Officer, Mymee

9:10 Presentation - Digital Therapeutics: Pursuing the Next Phase of Industry Evolution

Megan Coder, Executive Director, Digital Therapeutics Alliance

Pharma & Digital Therapeutics

9:25 Presentation - Commercializing and Scaling Prescription Digital Therapeutics

- A look at how Sandoz are incorporating digital therapeutics into core business units
- Case studies focusing on commercializing and scaling a digital therapeutic from deal-signing until now
- Discussion will focus on the lessons learnt so far from the partnership with Pear Therapeutics

André Heeg, Head of Digital, Sandoz

9:50 Panel - Pharma and Digital Therapeutics: A Match Made in Heaven?

After the announcement of the first pharma-digital therapeutic partnerships and more pharma deciding their involvement, there are plenty of questions around the short and long-term goals of these partnerships. This panel will focus on the different kinds of partnerships and what expectations pharma have on a day-to-day basis and at the strategic level. Discussion will focus on:

- Operationally, how do you actually combine tech with drugs into a unified product?
- How do pharma apply their learnings from working with companion products to digital therapeutics?
- At what level do pharma "value" the addition of digital therapeutics to their strategies?
- Are pharma more excited about the therapeutic entity of digital therapeutics or the data they produce?
- What do digital therapeutic companies look for when analyzing what pharma to work with?
- How much are pharma anticipating that consumer behaviour will drive patient adoption and engagement?
- How do we position and convey the value of digital therapeutics to research groups if you can't mechanistically see how digital therapeutics work?
- How much will digital therapeutics launches be treated the same as a drug launch in pharma?

Seth Coombs, Vice President, Oncology & Injectable Products, Sandoz

David Klein, Chief Executive Officer, Click Therapeutics

Ruchita Sinha, Senior Director, Investment, Sanofi Ventures

Jeremy Sohn, VP & Global Head, Digital Business Development & Licensing, Novartis

Javier Garcia Palacios, Director, Digital Health Ventures, Bayer, #G4A

10:35

Morning Refreshments & Networking

The Next Wave of Digital Innovation

11:05 Presentation - European Perspective on Digital Therapeutics - Fitting into Universal Healthcare Systems and Beyond

- A look at how GAIA have been integrating digital therapeutics into healthcare systems in Europe and beyond
- Case studies showcasing how GAIA have been developing robust digital therapeutic pipelines for over a decade
- Discussion will focus on how digital therapeutics are viewed in Europe, generally speaking

Matthias Zenker, Partner, GAIA AG

11:30 Presentation - Evidence-based Digital Interventions Using Music and Neuroscience

- A look at how a digital therapeutic company is pioneering the application of the neuroscience of music as a proven therapeutic for acute and chronic neurological populations that impact the motor system
- The discussion will focus on the science behind the approach, the gathered evidence, and how this is presented to regulators, investors, and payers
- The team discusses how it operationally packages their product in the healthcare system and pipeline of DTx indications in their future

Brian Harris, Co-Founder & CEO, MedRhythms Inc.

11:55 Presentation - Pivoting from Digital Health to Digital Therapeutics in Alcohol Behavioural Change

- Discussion will focus on the success Hello Sunday Morning have achieved through a more B2C approach
- A look at the reasons why Hello Sunday Morning have decided to pivot to Digital Therapeutic development
- What are the expectations of the impact we will have and the challenges we will face?

Chris Raine, Founder & Chief Executive Officer, Hello Sunday Morning

12:20 Presentation - How to Build and Scale Digital Therapeutics in Emerging Markets?

Abhishek Shah, CEO, Wellthy Therapeutics

12:45

Long-Table Lunch & Networking

Digital Therapeutic Market Consolidation

1:45 Panel - How and When Will the Digital Therapeutics Market Consolidate?

There is no doubt that digital therapeutics offer an exciting new opportunity to translate the potential of digital health into genuine treatment options. With this interest comes a lot of innovation and a swell of new companies but how will the industry mature? This closing panel session will focus on current predictions of how the winners and losers will emerge and what this will mean for the long-term future of the industry. Takeaway discussion will focus on:

- What are the current predictions of how the digital therapeutic market will mature and consolidate over the next five years?
- How do we balance embracing innovations v.s. improving the more standard approaches as the industry matures?
- What impact will the first influx of meaningful revenue from prescription digital therapeutics have on the market?
- How will investors change their strategies as the market matures?
- Is market convergence a good thing for pharma and biotech?
- What are the take home messages for attendees from this Summit in relation to the future of the industry?

David Kim, CEO, **DigiTx Partners**

Owen McCarthy, Co-Founder & President, MedRhythms Inc.
Shahram Seyedin-Noor, Founder & General Partner, Civilization Ventures

2:35 Chair's Summary

- What have been the key lessons learnt from the DTx West 2019?
- What are we expecting the industry to look like at DTx West 2019?
- What do we want to be discussing at DTx East 2019?

Mette Dyhrberg, Chief Executive Officer, Mymee

2:45 Close of DTx West 2019