



DTx LONDON

Conference Day 1, Tuesday June 9th, 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 how the preferred business model may change from country to country

Led By:

Matthias Zenker, Partner, **GAIA AG**

Kim Baden-Kristensen, Co-Founder & CEO, **Brain+**

Ed Cox, Chief Executive Officer, **Dthera**

Agenda

9:00am Panel Discussion: 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 regulated and Non-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?
- 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
- An understanding of the current successes of business models in varying countries across Europe
- A clear understanding of current routes to market and their intricacies
- Your questions answered by industry leaders and your peers

End of Workshop

Conference Day 1, Tuesday June 9th, 2020

Workshop 2 - A Deep Dive into the European Regulatory Landscape

The regulatory landscape across Europe is complex and varied in comparison to the U.S counterparts. With numerous regulatory bodies and different requirements for each, scaling across Europe can prove challenging. This workshop, led by leaders of the industry, will provide you with answers to your key questions on European Regulation, new inbound regulatory changes and how best to move forward with achieving pan-European approval for digital therapeutics.

Led By:

Jessica Schull, European Lead, **Digital Therapeutics Alliance**

Ray Pinto, Policy and Member Relations Director, **DIGITALEUROPE**

Agenda:

1:00pm Panel Discussion: A Top Level View of the European Regulatory Landscape - The Old & The New

- A look at the current standards of regulation across Europe for digital therapeutics
- What are some of the new regulatory standards being introduced into Europe and how does

it affect DTx?

- How can DTx companies best connect and work with regulatory bodies for success across Europe?

1:40pm Breakout Discussions

Splitting into smaller groups, you will discuss the intricacies of the regulatory landscape across Europe and hear views on how best to interact with the regulatory bodies.

- How does regulation for digital therapeutics differ country to country across Europe?
- Is it possible to achieve pan-European digital therapeutics regulation?
- How do the new Medical Device Regulation updates affect achieving regulatory approval for digital therapeutics?

2:30pm Refreshment Break

3pm 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 clear understanding of the European regulatory landscape
- A deeper understanding on how best to tackle the varying Regulatory bodies across Europe
- An understanding of how the new MDR changes will affect the DTx industry and how best to adhere to them
- Being in the know for future plans for a pan-European regulation for digital therapeutics
- Your questions answered by industry leading experts and your peers

End of Workshop

Conference Day 2, Wednesday June 10th, 2020

8:00am Registration, Breakfast & Networking

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

Ciara Clancy, CEO, **Beats Medical**

9:10am Presentation: **Big Health & NHS**

- An update on the success of Sleepio within the NHS
- Has the implementation of Sleepio within the NHS gone exactly to plan?
- What are the lessons learned from this partnership moving forward?

Colin Espie, Co-Founder & CMO, **Big Health**

9:50am Panel: **What are the Go-To-Market Models Where we can Expect to Find Success in Digital Therapeutics?**

The digital therapeutics landscape is both multifaceted and multilateral with many different companies taking different approaches. In an industry that has seen both success and failures from many areas, this panel will explore the in's and out's of taking digital therapeutics to market and identify if there is truly a best practice approach.

- What are some of the successful GTM strategies we have seen in the DTx industry?
- How do GTM strategies differ across the European landscape?
- Is there a "one size fits all" GTM model that can be adopted or does each have to tweak depending on the digital therapeutic?

Moderated by **Kim Baden-Kristensen**, Co-Founder & CEO, **Brain+**

Brent Vaughan, Chief Executive Officer, **Cognoa**

Charlotte Lee, Director, **Big Health**

Marianne Veighey, Director, Head of Intelligent Pharmaceuticals, **AstraZeneca**

10:30am

Morning Refreshments

DTx London 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

Track 1

Deciphering Growth and Commercialisation for Digital Therapeutics

Chair: **Ciara Clancy**, Co-Founder & CEO, **Beats Medical**

Track 2

Front Line Considerations for Digital Therapeutics

Chair: **Elena Mustatea**, Chief Executive Officer, **Bold Health**

<p>11:30am Presentation: Scaling across the EU - Challenges, Barriers and Successes</p> <ul style="list-style-type: none"> • What considerations need to be taken into account when scaling across the European landscape? • What are the greatest challenges in scaling between countries? • An insight into Happify's journey in scaling from the US and across Europe <p>Acacia Parks, Chief Scientist, Happify</p>	<p>11:30am Presentation: It's Not Good Enough to Have a Good Intervention</p> <ul style="list-style-type: none"> • What other variables alongside the intervention are required for DTx success? • A case study on how SilverCloud Health have built a successful digital therapeutic? <p>Derek Richards, Chief Science Officer, SilverCloud Health</p>
<p>11:55am Panel Discussion: The Regulatory Story within the European Landscape</p> <p>With the digital therapeutics industry scaling rapidly across Europe, the differences in regulation between countries prove to be challenging. This panel will dive into the intricacies of the European regulatory landscape and also explain some of the new regulatory framework being introduced in 2020.</p> <ul style="list-style-type: none"> • Are the different regulatory bodies across Europe making it harder for digital therapeutics to scale effectively? • A look at the work the DTA are doing to create a common European HTA framework • Is it possible to achieve pan-European regulatory approval with such a diverse landscape? • What are the new MDR updates and what does this mean for digital therapeutic companies? <p>Jessica Shull, European Lead, Digital Therapeutics Alliance Dennis Hermann, VP, Business Development, Kaia Health</p>	<p>11:55am Panel: From Clinic to Clinician - Achieving Adoption at Scale in the Clinic</p> <p>Digital therapeutics have demonstrated both clinical and commercial success. However, getting the therapies into the hands of the patients mostly sits with the prescribing clinicians. This panel will dive into how best to get DTx smoothly integrated into the hands of clinicians.</p> <ul style="list-style-type: none"> • How can we ensure that we are achieving smooth integration of DTx into the clinician workflow? • What steps can we take to increase patient adoption? • Does there need to be an incentive scheme for clinicians prescribing DTx & what are the intricacies of this? • How can we promote patient engagement and longevity of DTx use? • How can DTx be effectively integrated into electronic health records? <p>Edouard Gasser, CEO, Tilak Health Hakim Yadi, Co-Founder & CEO, Closed Loop Medicine Mala Mawkin, Medical Doctor, Southend University Hospital NHS Trust Foundation</p>
<p>12:35pm Lunch and Networking</p>	

<p>2:00pm Presentation: Scale, Expansion and Partnerships - A Case Study by NuvoAir</p> <ul style="list-style-type: none"> ● A look at how NuvoAir’s recent partnership with Roche came to light ● How are NuvoAir tackling breaking into both the European and American markets? <p>Lorenzo Consoli, CEO & Founder, NuvoAir</p>	<p>2:00pm Presentation: User-centric solutions to drive satisfaction, engagement and outcomes</p> <ul style="list-style-type: none"> ● How to build and scale up user centric offering ● How user satisfaction can drive engagement and clinical outcomes ● A case study on how Dario Health are putting users first to drive success <p>Erez Raphael, CEO, Dario Health</p>
<p>2:25pm Panel: How to commercialize across Europe and is Pharma the key?</p> <p>Commercialisation of DTx has always been a challenge and pharma partnerships have been both made and broken. This panel is set to deep dive on commercialising digital therapeutics and officially put DTx and Pharma partnerships under the microscope</p> <ul style="list-style-type: none"> ● Is there a best practice for commercialisation in the European Market? ● What are the opportunities for commercialisation? ● Is pharma the key for commercialisation and scalability or are DTx companies able to take on this role themselves? <p>Alexandre Capet, Chief Operating Officer, Voluntis Francesca Wuttke, Chief Digital Officer, Almirall Tryggvi Thorgeirsson, Co-founder & CEO, Sidekick Health Junaid Bajwa, Global Lead for Strategic Alliances, Digital Centre of Excellence, Merck</p>	<p>2:25pm Panel: Serving the Patient: It’s Not About Us, Without Us</p> <p>The digital therapeutics industry is young, but maturing rapidly. Looking to replace or partner with existing traditional therapies, DTx is set to make waves in the industry. One challenge now is ensuring that patients engage with DTx initially and at length. This panel will deep dive into how best to do just that.</p> <ul style="list-style-type: none"> ● What do patients really think of digital therapeutics? ● Are patients truly ready to step away from the traditional with the implementation of DTx? ● Are some groups naturally excluded from DTx use and how can this be tackled? <p>Donna Walsh, Executive Director, EFNA Dom Raban, Chief Executive Officer, Xploro Marianne Veighey, Director, Head of Intelligent Pharmaceuticals, AstraZeneca Jenny Christensson, Chief Patient Officer, Elsa Science</p>
<p>3:05pm Afternoon Refreshments and Networking</p>	
<p>4:05pm Panel: Leveraging Real World Evidence on Consumer Utilization and Clinical Aspects to Drive Performance Based Models with Payers?</p>	

To effectively approach payers for reimbursement opportunities, a digital therapeutics company needs to provide a plethora of clinical and user-based data to prove the therapeutic works. However, there is no handbook on what data needs to be demonstrated. This panel will dive into the intricacies of how to effectively engage with payers to achieve reimbursement.

- What information do payers need to see to proceed with partnership and reimbursement of a DTx product?
- Is there a bar of validation for real data evidence that payers need to see met or does this work on a case by case scenario?
- How are DTx companies expected to provide consumer utilization data prior to being reimbursed and commercialised? Is this a 'chicken and egg' scenario?

Erez Raphael, CEO, **Dario Health**

Elena Mustatea, Chief Executive Officer, **Bold Health**

Steve Burns, VP, Product Development & Digital Therapeutics, **AstraZeneca**

Ali Hasan, Chief Medical & Healthcare Officer, **Vitality Health**

4:45pm **Chairs Closing Remarks**

Ciara Clancy, CEO, **Beats Medical**

5:00pm **Drinks Reception**

6:00pm **Close of DTx London Day 1**

Conference Day 3, Thursday June 11th, 2020

8:00am **Registration and Networking**

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

Edouard Gasser, CEO, **Tilak Health**

9:10am Presentation: **Keeping in Theme - An indepth look at Implementation and Outcome of Cognoa's DTx Online Clinical Trials**

- Why did Cognoa decide to move away from traditional trials and run them online?

- A brief discussion on whether DTx clinical trials should always be online
- The results of Cognoa's online clinical trials

Brent Vaughan, Chief Executive Officer, **Cognoa**

9:35am Panel: **What do investors really think about 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

- What do investors need to see from DTx companies to pull the trigger on their investments?
- 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?
- How has the investor view changed since DTx Europe 2019?
- Now we have begun to see exits in this space, how has the investor perspective changed?

Rana Lonnen, Head Search & Evaluation Strategic Venture Capital, **Novartis**

Edward Kliphuis, Investment Director, **M Ventures**

Heather Roxborough, Partner, **Optum Ventures**

Lana Ghanem, Managing Director, **Hikma Ventures**

10:15am

Morning Refreshments and Networking

11:10am Presentation: **Commercialising Digital Therapies for Neurological and CNS Conditions**

- An update on the commercialisation of Beats Medical
- What are the challenges and lessons learnt since our last update at DTx Berlin?
- What are the plans for Beats Medical moving forward?

Ciara Clancy, CEO, **Beats Medical**

11:35am Presentation: **The Effectiveness of a Novel Digital Tobacco Cessation Program with Carbon Monoxide Monitoring with US Employers**

- A deep dive into Quit Genius - the smoking cessation app
- An insight into Quit Genius RCT's and the accompanying results
- A look at Digithera's partnerships with US employers

Maroof Ahmed, Co-Founder & COO, **Quit Genius**

12:00am Presentation: **Presentation by Lucine**

Maryne Cotty-Eslous, Founder, **Lucine**

12:25pm

Lunch and Networking

1:25pm Panel: **Choosing the 'Right' Business Model for you**

In an industry where no two approaches are the same, it's crucial to seek out and identify early on in a company's development journey which business model is most likely to bring them success. With so many already in use, the question is which one is best you personally and how do you choose it. This panel will dive into all of this and more.

- What are some of the business models that have seen success in the European Market?
- A look at the challenges for B2B, B2B2C, B2C and B2G models
- Is one strategy proving to be more successful than the other?
- Is there a 'best practice' business model out there for Europe or do we have to adopt new strategies as we cross borders?

Moderated by **Ed Cox**, Chief Executive Officer, **Dthera**

Matthias Zenker, Partner, **GAIA AG**

Ashish Patel, Principal, **Optum Ventures**

Carmen Rios, VP, International, **Limbox**

2:05pm **Chairs Closing Remarks**

Edouard Gasser, CEO, **Tilak Health**

2:15pm **End of DTx London 2020**