



Defining the New Age of Digital Therapeutics

28th-29th June 2022

London, UK & Online | 4th Annual

Conference Day 1: Tuesday, 28th June 2022

8:00am BST **Registration, Breakfast & Networking | Conference Platform Opens**

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

Lina Behrens, Managing Director, **Flying Health**

Commercialisation & Reimbursement

9:10am BST **Keynote Fireside Chat - The Current Landscape of the European DTx Market: Where Are We Now?**

It is without doubt the DTx industry has made great leaps over the past few years coming off the back of the COVID-19 pandemic, technological advancement, and changes in legislation. Following industry developments such as DiGA it is essential to observe and learn from what has worked, and what may have not worked, from implementing new strategies. This conversation will outline what the European DTx landscape looks like today, looking into some of the differences and similarities between the various markets in European countries.

- Where has the market landed two years post-pandemic?
- Is the DTx market maturing at the right pace?
- What have we learnt from DiGA?
- How does DiGA in Germany differ from other reimbursement pathways coming to life within Europe e.g France, Belgium, UK, Italy?

Matthias Zenker, Chief Medical Solutions Officer, **GAIA AG**

Hélène Moore, Executive VP & Head of Digital Therapy, **Ethypharm**

9:35am BST **Panel Discussion - A Deep Dive Into The Future of Digital Health Reimbursement Pathways in Europe**

Reimbursement pathways within the European space are continuing to open up. Countries seem to be following the footsteps of Germany as we see France implement a similar plan to DiGA. Is replicating what Germany has done with DiGA going to be the viable route for success in the European market or are we heading in the wrong direction? This session will discuss the future of reimbursement pathways in Europe, diving into the challenges that may be faced ahead.

- Is it possible for France to duplicate what Germany has done with DiGA? Is this the solution?
- Is a centralised reimbursement pathway a viable option for the future of the European market?
- What steps must be taken?
- If a centralised model came to fruition, how will this affect countries outside of the EU?

Moderator: **Kate Bennet**, Senior Principal Life Sciences, **IQVIA**

Kathrin Pfeiffer, Head of Market Access, **Sympatient**

Catherin Pollard, Joint Head of the NHS Digital Policy Unit & Director of Tech Policy, **NHS**

Louisa Stuwe, eHealth Project Lead for French EU Presidency, **French Ministry of Health**

10:15am BST

Morning Refreshments and Networking

Partnerships

10:55am BST **Panel Discussion - An Overview into the Key Considerations of Pharma Partnerships Working with DTx Companies**

Digital therapeutic and pharmaceutical company partnerships have played an instrumental role in growing the field ever since the industry began. As the market matures and both parties develop their understanding of how to work with one another the criteria for making an effective partnership evolves alongside. Here, we will explore what pharmaceutical and DTx companies have learnt from working with one another and how that has changed the current landscape of forming partnerships to come.

- Is pharma the answer for all DTx companies?
- How can digital tools be incorporated into a pharmaceutical company's product range to benefit business?
- Which digital therapeutic products are of more interest to pharmaceutical companies?
- Is the criteria for DTx companies partnering with pharmaceutical companies changing?
- How can pharmaceutical companies add value to DTx companies?
- What are the fundamental barriers to scaling digital therapeutic products?
- What will be the value drivers to put digital tools in the hands of the consumer?

Moderator: **Jessica Shull**, Head of Digital Therapeutics, **Vicore Pharma**

Jin Lee, Director of Digital Health, **Astellas**

Sarah Beeby, UK Managing Director, **Liva**

Dominick Kennerson, Global Head G4A - Digital Health Partnerships, **Bayer Pharmaceuticals**

Susanne Gruber, VP of Pharma Partnerships, **Sidekick Health**

Quentin Le Masne, Head of Development & Innovation - Connected Health & Devices, **Merck Group**

11:40am BST **Fireside Chat - Are Exit Strategies the Future Direction of Life Science Partnerships?**

- An insight into the process of Aptar acquiring a Voluntas
- Reviewing the benefits of DTx platforms focusing on exit strategies over going public
- Is an acquisition of a DTx company a viable exit strategy for others looking forward?

Sai Shankar, President of Digital Health, **Aptar Pharma**
Pierre Leurent, CEO & President of Digital Health, **Voluntis | Aptar Pharma**

12:20pm BST

Lunch & Networking

Clinical Insights & Regulation

1:50pm BST **Presentation - How Intelligent Healing Bridges the Gap Between Regulation and Precision Medicine**

The regulation laws necessary for the development of clinical products using precision medicine to ensure patient protection and encourage innovation remains a challenge. The use of Artificial Intelligence can enable precision medicine systems to reason and learn, allowing for clinical products to personalise its effect to an individual based on their condition. This session will assess how AI may be used in precision medicine to follow governmental guidelines.

- Regulatory requirements state all patients must receive the same version of a treatment
- Can AI fit the regulatory model whilst personalising medical treatments to individuals?
- Will this be the future direction for digital medicine?

Chris Wasden, Head of Pharma Speciality Solutions & Corporate Strategy, **Happify Health**

2:15pm BST **Presentation – How Adaptive Machine Learning Algorithms Can Safely be Integrated into Regulated Digital Platforms**

The inclusion of AI-driven algorithms in Software-as-a-Medical-Device (SaMD) digital health and digital therapeutic applications has historically focused on rules-based and deterministic AI methods, due to their inherent traceability attributes that satisfy both patient personalisation as well as safety requirements by the regulatory agencies. But, with the explosive velocity, variety, volume, and veracity associated with data capture in these software platforms, the application of the machine-learning side of AI has the potential to increase the precision and personalisation of therapies, to ultimately drive even better health and economic outcomes. WellDoc, a leader in leveraging digital health to revolutionise chronic condition management, explores how adaptive machine learning algorithms can safely be integrated into regulated digital platforms.

- Re-introduce their IDEA(™) framework to understand how ML can help Inform, Discover, Extrapolate and Adapt(™) data to drive personalization.
- Review recently published guiding principles from the U.S. Food and Drug Administration (FDA), Health Canada, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), and International Medical Device Regulators Forum (IMDRF) to advance good machine learning practices.
- Demonstrate the initial use of these methods with a novel integration of ML algorithms to detect continuous glucose monitoring events that help drive enhanced patient coaching.

Dr Anand K. Iyer, Chief Strategy Officer, **WellDoc**

2:40pm BST **Presentation - Randomised Controlled Trials in DTx: How Unique Approaches are Needed for Digital Therapeutic Studies to Emulate Placebos, Blind and Randomise**

- DCTs are the future of delivering digital therapeutics - unique approaches are required to deliver regulatory grade requirements for studies typical of pharma studies
- Randomisation presents many challenges in traditional studies, but digital therapeutics present unique challenges to assign treatment groups
- Placebo controls typical of pharma companies are more difficult to emulate in DTx studies. Explore use of sham and control arm applications.

Whitney Stewart, Director of Clinical Project Management, **Curebase**

3:05pm BST **Panel Discussion - Exploring a Need for Change of Clinical Trials in Digital Medicine**

The current framework for clinical trials in digital health falls under an umbrella of one size fits all. There is an unwritten dichotomy between regularly updated software based digital health products and how regulatory frameworks are designed. This panel of experts will dive deep into discussing the need for innovation in policy of clinical trials.

- What are the key challenges facing the European market in clinical trials today?
- How can we utilise decentralised clinical trials to bring value to the DTx industry?
- How do decentralized clinical trials compare to traditional studies?
- Where can changes be made within the clinic to develop more efficient trials for DTx?
- What changes must be made in regulation to accommodate for new digital medicine?
- Companies are trying to innovate software fast in DTx but regulatory issues are getting in the way, how can we combat this?
- How much of an algorithm can change for its regulatory classification to change?

Moderator: **John Renander**, Co-Founder & CEO, **Alex Therapeutics**

Jorge Palacios, Senior Digital Health Scientist, **SilverCloud Health**

Nora Blum, Co-Founder & CEO, **Selfapy**

Martin Culjat, Senior VP, Regulatory Innovation & Digital Medicine, **Eversana**

3:45pm BST

Afternoon Refreshments & Networking

4:25pm BST **Presentation - An Overview of the DTx Value Assessment & Integration Guide**

- Given the recent growth of the DTx industry and lack of frameworks defining what “good” looks like, many HCDMs have taken it upon themselves to develop their own methods to evaluate DTx products.
- This Guide serves as a tool for HCDMs and DTx manufacturers to use in assessing baseline information about the product, its value, and impact in real-world settings as they enter into product access and contracting discussions.

Megan Coder , Chief Policy Officer, Digital Therapeutics Alliance	
4:50pm BST Presentation - DTx Adoption in Germany: Prescription Patterns From GPs and Specialist Practices	
Michael Renz , Key Account Manager MedTech, IQVIA	
5:15pm BST Presentation - Digital Solutions to Transform Mental Healthcare	
<ul style="list-style-type: none"> - Why clinical data is key to making progress in mental health - Using real-world data to improve mental healthcare and recovery rates - Our key learnings in the last decade in developing digital tools for mental healthcare assessment and treatment 	
Andrew Welchman , Executive VP for Impact, ieso	
5:40pm BST Panel Discussion - How Do We Move Forward? - Breaking DTx into The Mainstream Healthcare System	
<p><i>As some countries in the European market await for changes in reimbursement laws, it is essential the industry begin to blueprint how products can be scaled. The existing models that are currently used for commercial traction being applied to pharmaceuticals will not translate to DTx directly. This panel will dive into how the industry can begin to tackle and innovate new commercial strategies for DTx products.</i></p>	
<ul style="list-style-type: none"> - What commercial barriers are holding DTx companies back from entering the popular market? - How must we innovate commercial models to grow a company's revenue? - How shall DTx companies be allocating their commercial budgets? - What are the best practices in developing, scaling and maintaining a successful DTx company? - What are the greatest challenges to scaling a digital therapeutics product across multiple markets in Europe? 	
Moderator: Francesca Wuttke , Founder & CEO, nen	
Ali Hasan , Chief Medical Officer, Vitality	
Dennis Hermann , VP of Finance and Business Development, Kaia Health	
Mala Mawkin , Chief of Staff, Leva Clinic	
Itamar Grotto , Full Professor, Ben Gurion University	
6:20pm BST Chairs Closing Remarks	
Lina Behrens , Managing Director, Flying Health	
6:30pm BST	Drinks Reception & Networking
7:30pm BST	Close of DTx Europe 2022 Day 1

Conference Day 2: Wednesday, 29th 2022

8:00am GMT **Registration, Breakfast & Networking | Conference Platform Opens**

9:00am GMT **Chairs Opening Remarks & Setting the Scene**

Christian Angern, Co-Founder & Managing Director, **Sympatient**

Adoption

9:10am BST **Keynote Presentation - What Are The Fundamental Barriers to Physician Adoption in Digital Therapeutics?**

Public perception may have changed due to the COVID-19 pandemic but how has this impacted physician adoption? In this session we shall assess what the future holds for DTx adoption and what steps must be taken to break down this wall.

- What are the key obstacles within physician adoption?
- How has COVID-19 changed people's perspective and engagement of digital health tools?
- Has increased awareness and necessity of digital health tools had a significant impact on adoption?
- How are we going to address these barriers?

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

9:35am BST **Presentation - Launching and Scaling DTx Products in the United States**

Tremendous tailwinds have created an exciting environment for Digital Therapeutics in the United States, ranging from emerging business models and reimbursement pathways, as well as increasing clarity from the US FDA on how it will regulate DTx solutions. As a result, DTx companies are now gaining traction and interest from all members of the ecosystem, including providers, payers, employers, pharma as well as other digital health and telehealth companies.

- Current headwinds and tailwinds facing DTx companies in the United States
- Market activity among various buyers (providers, payers, employers, pharma) as it relates to DTx solutions
- Key considerations on how to assess whether your DTx solution will succeed in the US

Kamal Jethwani, Co-Founder & CEO, **Decimal.health**

10:00am BST **Panel Discussion - Putting the Product in Patients Hands: How to Increase Physician Adoption?**

- Even with developments like DiGA physician adoption is still low
- How can physicians adapt their workflow to make digital health a reality?
- What do physicians need to see to begin incorporating digital therapeutics into their workflow?
- Is it true that digital therapy could lead to people losing jobs in the long-term?
- As Europe is maturing as a market, how will companies get their products in the hands of patients?
- Are education campaigns going to be the final hurdle to take DTx products to the next phase?

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

Rayna Patel, Co-Founder & CEO, **Vine Health**

Lucy Jones, VP of Clinical, **Oviva**

Venkat Reddy, Officer for Digital Health and Technology, **Royal College of Paediatrics and Child Health**

10:40am BST

Morning Refreshments & Networking

User Engagement & Consumer Awareness

11:20am BST **Presentation – How to set up a successful marketing and sales approach for DTx?**

Once you've achieved reimbursement, the focus will shift towards marketing and sales. In this session, we will discuss examples for DTx approaches in the market, and what can be learnt from them.

- Physicians and patients – how can these two different audiences be addressed?
- What are selected legal requirements to keep in mind when setting up your marketing approach?
- How do other DTx companies approach sales and marketing, and what can be learnt from them?

Lina Behrens, Managing Director, **Flying Health**

11:45pm BST **Presentation - Gamification: A Tool for Increasing User Engagement in Digital Health**

- How can gamification be used in different ways to increase user engagement?
- What does gamification bring to DTx and how can this be used alongside other inputs?
- What comparisons can be made between digital tools that incorporate gamification to those that do not?

Eduoard Gasser, Co-Founder & CEO, **Tilak Healthcare**

12:10pm BST **Presentation – “In The Long Run”: A Behavioural Change Focused Approach to Digital Health**

- What lessons can digital health learn from consumer industries to deliver long-term, consistent user engagement?
- How can digital therapeutics adopt a user-focused mindset to create a behavioural change with patients?
- Where do the benefits of long-term interaction overlap for patients, providers and the healthcare ecosystem?
- An insight into Beats Medical's approach – changing the approach to patient engagement by creating lasting value

Joao Planche, VP of Design, **Beats Medical**

12:35pm BST **Panel Discussion- How Can We Ensure Longevity of Digital Health Products Through Consistent User Engagement?**

- What makes a successful DTx product?
- What strategies are in place to keep users engaged over long periods of time?
- How are DTx companies trying to increase consumer awareness and intimacy?
- What are the reservations of digital therapeutic products and how can we tackle these?
- An insight into how companies can gather and utilise patient engagement, usage, and retention data to increase consistent engagement with new users

Moderator: Eduoard Gasser, Co-Founder & CEO, **Tilak Healthcare**

David Boutellier, Head of Europe, **Kaia Health**

Paula Petcu, Chief Technology Officer, **Brain+**

Andrew Phelan, Chief Operating Officer, **Beats Medical**

Panos Papakonstantinou, Global Digital Engagement Catalyst Leader, **Roche**

1:20pm BST **Chairs Closing Remarks**

Christian Angern, Co-Founder & Managing Director, **Sympatient**

1:30pm BST

End of DTx Europe 2022