

22nd-24th February | 2023 | Bay Area, Ca | 6th Annual

Conference Day 1: Wednesday, 22nd February 2022

9:00am Chairs Opening Remarks and Setting the Scene

Amber Trivedi, Chief Operating Officer, Blue Note Therapeutics

9:10am Keynote Panel Discussion: What are the Building Blocks for Making a Successful Digital Therapeutic in Healthcare Today?

- How has digital healthcare evolved over the past 5 years?
- What does the current landscape look like today?
- What are the fundamental elements to making a successful digital therapeutic product?
- Are some factors more impactful than others? Where should companies focus their attention?
- Where do digital healthcare companies seem to be tripping up?

Moderator: Shaheen Lakhan, Chief Medical Officer, Click Therapeutics
Shah Nawaz, Chief Technology Officer / Vice President of Digital Technologies & Engineering, Regeneron Edmondo Robinson, Chief Digital Officer, Moffitt Cancer Center
Laura Yecies, Chief Executive Officer & Board Member, Bone Health Technologies
Jodi Prohofsky, Chief Operating Officer, ieso

9:50am Keynote Panel Discussion: Details Matter: The Evolution of Evidence Standards in Digital Health

Digital health evidence standards are evolving rapidly. More than 60 frameworks have been proposed to assess evidentiary support for digital health interventions. This poses challenges to digital health solutions providers (DHSPs) who wish to generate compelling clinical evidence. How might current standards of evidence quality change by the time a trial concludes? Which standards are most aligned with an organization's vision and strategy? This session will address the past, present, and ideal future states of evidence standards for digital health interventions. We will discuss concrete steps that may help DHSPs future proof their evidence generation strategy in this rapidly evolving space. Key gaps in the field will be explored. Finally, our expert panel will suggest concrete steps that may help close current gaps and accelerate progress in digital health.

- Understand concrete steps that may help digital health solutions providers "future proof" their evidence generation strategy.
- Increase understanding around the current state of evidence standards in digital health.
- Appreciate the importance of "fundamentals" in digital health trials.`
- Know how to avoid common pitfalls in evidence generation for digital health interventions.
- Increase awareness of key gaps and opportunities to advance the field.

Moderator: Jordan Silberman, Director of Clinical Analytics & Research, Elevance Health

Jennifer Goldsack, CEO, Digital Medicine Society

Steve Schwartz, Chief Science Officer, The Larsen-Kufahl Group

David Klonoff, President, Diabetes Technology Society | Clinical Professor of Medicine, U.C San Francisco

Siavash Sarlati, Medical Director, Digital Care Delivery, Elevance Health

Anindita Saha, Assistant Director, Digital Health Center of Excellence, FDA

	:3		

Morning Refreshments & 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.

Track	<u>1 -</u>	Ballr	<u>oom</u>	APC

Value

Chaired by **Jennifer Lavanture**, Vice President of Business Development, MedRhythms

Track 2 - Ballroom D

Evidence

Chaired by Amber Trivedi, Chief Operating Officer, Blue Note Therapeutics

11:00am Presentation: Dawn Health Announces a New Partnership to Transform the Treatment of Chronic Diseases

- Digital Health products are changing disease management, however, the balance between speed, impact and patient engagement is still suboptimal
- The Dawn Platform reduces time-to-market for SaMD and DTx products, and our best-in-class services deliver unique levels of

11:00am Presentation: The Do's and Dont's When Running a Digital Therapeutics Clinical Trial

- Important factors not to overlook in running a digital health clinical trial
- What can new companies entering the industry do to ensure they launch an effective clinical trial?
- What does a 'good' clinical trial look like?

engagement
The Founder & CEO reveals a novel partnership between Dawn
Health and a leading Pharma company on stage

Daniel Daugaard, Founder & CEO, Dawn Health

11:25am Presentation: Digital Care for All: How Digital Therapeutics Are Solving Global Healthcare Challenges

- Learn about novel applications of DTx in Asia and other Emerging markets
- Understand how solutions in Asia and emerging markets are solving similar challenges faced in the US/EU
- Discuss how DTx companies, providers, payers and other stakeholders from the US/EU can leverage emerging market models
- Discuss how DTx companies in Asia and emerging markets can access US/EU markets

Theo Ahadome, Chief Business Officer, Wellthy Therapeutics

Jessica Lake, Chief Science Officer, Limbix

11:25am Presentation: Conducting Quality-Driven Trials for Digital Therapeutics

- A review of key regulations applicable to DTx research
- What to consider when selecting vendor partners for your study
- Common challenges seen in DTx trials and how to pivot if/when they arise

Whitney Stewart, Director of Clinical Project Management, Curebase

11:50am Panel Discussion: Creative Commercial Pathways - What Else Works?

- There are several commercial models that exist for DTx outside of those seeking claims-based reimbursement as PDTs
- Highlight differences in product profiles between PDTs and those using alternate commercial models
- Discuss potential customer segments employers, providers, health plans both through claims and through vendor
- Share examples of DTx, digital health, and virtual care companies and products that use these various models
- With reimbursement and adoption continuing to be an obstacle, how are companies innovating business models to maintain growth?
- Who should DTx companies be thinking of partnering with to help scale-up business?
- What actions must we see moving forward from all stakeholders in the industry to break DTx in mainstream healthcare?

Moderator: **Kenichiro Nishii**, Lead, Regulatory Affairs & Business Development, **CureApp**

Adam Kaufman, Former GM & SVP, Healthcare & Diabetes, Formally WW John Drakenberg, Co-Founder & CEO, Alex Therapeutics

Patricia Bradley, Chief Commercial Officer, MindMaze

11:50am Panel Discussion: Adapting the Future of DTx Clinical Trials

- An outline of the current state of affairs within digital health clinical trials
- Are we where we expected to be today?
- What are the fundamental barriers that affect digital therapeutic clinical trial pathways?
- What are the pros and cons of using decentralized clinical trials over a site-based system?
- How are companies working to combat concerns regarding socio-economic, gender and racial equity in clinical trials?
- What seems to be holding decentralized clinical trials back from being fully adopted?
- How are companies planning to innovate clinical trials?
- Where must we see regulatory changes made to help reshape digital therapeutic clinical trials?
- How far do we still have to go and how do we get there?

Moderator: **Jessica McKinney**, VP, Medical Affairs and Clinical Advocacy, **Formally Renovia**

John Campbell, Head of Decentralized Trials, Walgreens
Athena Robinson, Chief Clinical Officer, Woebot Health
Jason Kahn, Chief Science Officer & Co-Founder, Mightier
John Kraus, Chief Medical Officer, Executive VP, Otsuka America
Pharmaceuticals Inc

Wessam Sonbol, Co-Founder & CEO, Delve Health

Lunch & Networking

2:00pm Presentation: Common Pitch Mistakes Causing Investors to "Pass"...and How to Fix Them

Startup founding teams are finding it increasingly difficult to attract investment. By the time you recognize what mistakes you've made in your pitch, it's usually too late. You've missed an opportunity. Unfortunately, you'll never get a second chance to make that first impression.

- Goals of the pitch
- Understanding what your audience really wants
- Five catastrophic but common mistakes in your pitch
- A proven structure to follow
- How to adapt pitch materials for product intro conversations with customers

Matthew Tucker, Chief Commercial Officer, Nightware

2:00pm Presentation: Clinical Trial Innovation Using a High Sensitivity Digital Endpoints: A Case Study Using SV95C, the First EMA Qualified Digital Endpoint for Use in Pivotal Trials in Duchenne Muscular Dystrophy

- How high sensitivity digital endpoints can provide unique disease insights
- Regulators accept clinically meaningful digital endpoints for drug approval, when captured with valid and suitable technology
- Health authority qualified digital endpoints can revolutionize pivotal trial design and post-approval disease monitoring

Paul Strijbos, Neurotech Innovation Leader, Roche

2:25pm Fireside Chat: A Payor's Experience Using the DTA's DTx Value Assessment Guide

- The DTA Value Assessment 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.
- Here we explore a payer's experience using the Value Assessment Guide and observe their takeaways
- Is lack of education holding payers back from stepping over the line to reimburse digital health products?

Andy Molnar, Chief Executive Officer, Digital Therapeutics Alliance
Jason Parent, Director of Clinical Innovation, Point32Health

2:25pm Fireside Chat: "Having Your Cake and Eating It Too": A Discussion on How to Extract Value from Embedded AI in DTx While Ensuring Safety, Accessibility and Equity

- Can AI and machine learning be utilized in DTx be safely integrated in regulated digital platforms?
- If we can crack the code on how to harness AI to personalize healthcare whilst, will this be the future of digital medicine?

Anand Iyer, Chief Strategy Officer, Welldoc Megan Coder, Chief Policy Officer, Digital Therapeutics Alliance

3:00pm Afternoon Refreshments & Networking

3:30pm Presentation: Where is Digital Health Today? A Review by the NHS

Lily Tang, Deputy Director Digital Investment Strategy, NHS

3:55pm Panel Discussion: Successfully Innovating as Regulatory Science Evolves: In 2023, Where Do We Stand and What Do We Do Next?

Rapidly evolving landscape of digital therapeutics (DTx) are opening doors to a newer set of products, ranging from modern-day software-based medical devices to combinational drug-device products. Such development in the field is exciting and as a regulatory science evolves, brings with it a number of questions around such topics as level of regulatory science evolves, brings with it a number of questions around such topics as level of regulatory oversight, navigating pathways to optimize product strategies, evidentiary needs for regulated DTx products for decision-making and more.

- How can we see regulatory strategy become a commercial differentiator for digital therapeutics solution?
- How to bridge modern-day software-based medical devices with the new and past FDA regulations
- How can identifying the right regulatory pathway for your digital therapeutics impact reimbursement, patient adoption and health outcomes?

Moderator: Smit Patel, Director of Digital Medicine | Program Lead, Digital Medicine Society

Megan Coder, Chief Policy Officer, Digital Therapeutics Alliance

Imein Bousnina, Program Director, US Regulatory Policy, Genentech

Jennifer Goldsack, CEO, Digital Medicine Society

Saemundur Oddsson, Co-Founder & Chief Clinical Officer, Sidekick Health

4:45pm Chairs Closing Remarks

Amber Trivedi, Chief Operating Officer, Blue Note Therapeutics

5:00pm

Drinks Reception

6:00pm

Close of DTx West 2023 Day 1

Conference Day 2: Thursday, 23rd February, 2023

9:00am Chair Opening Remarks & Setting the Scene

Matthias Zenker, Chief Medical Solutions Officer, GAIA AG

9:10am Keynote Presentation: Going Beyond RPM/RTM - Creating real value for Providers and Patients with DTx

- As a follow-up talk from DTx East 2022, Dr. Jethwani continues his series on helping uncover the challenges and opportunities in gaining provider adoption for DTx solutions.
- Despite the significant tailwinds in the reimbursement landscape, recent reports have revealed a low level of adoption of these codes across the US. Many providers today either adopt DTx solutions without using these codes, or find the codes alone inadequate to justify adoption.
- In this session, Dr. Jethwani will discuss a framework to create value for providers and patients using DTx solutions, as well as talk about how this value can be translated to real revenue opportunities for DTx companies.

Kamal Jethwani, Managing Partner & Chief Executive Officer, Decimal.health

9:35am Keynote Fireside Chat: The importance of Science-Led Partnerships to Validate DTx Products and Reduce Health Care Costs

- There is a great need to build evidence around effectiveness and cost savings of DTx solutions
- Industry partnerships that align on this area have a greater chance of success
- Bright Therapeutics and Kaiser Permanente built a partnership that has research at its core
- The result is an innovative, science-led implementation of a DTx product that is improving the quality of eating disorder treatment
- This talk will cover how the various parts of the partnership come together from beginning to end, and the key drivers behind a successful, scalable implementation of a DTx product

Moderator: Jorge Palacios, Chief Science Officer, Bright Therapeutics

Jenna Tregarthen, Co-Founder and CEO, Bright Therapeutics

Stuart Buttlaire, Regional Director of Behavioral Health and Addiction Medicine, Kaiser Permanente

Samuel Ridout, Director of Research, San Jose Psychiatry, Kaiser Permanente

10:10am Keynote Panel Discussion: What are the Must-Haves Pharmaceutical Companies Look For In DTx - How has this Changed?

- What are key requirements pharma is looking for in digital health companies?
- Is pharma's criteria changing?
- Where should DTx companies focus their energy when seeking partnerships?
- What can pharmaceutical companies bring to DTx? When are pharmaceutical partnerships not the answer for DTx companies?
- Where does the future lie for DTx and Pharmaceutical partnerships?

Moderator: Sarah Jackson, Director of Business Development & Alliance Management, Click Therapeutics

Suhas Krishna, Vice President, Head of Product Management, Digital Health, Bristol Myers Squibb

Melinda Decker, Advisor and Fractional Chief Commercial Officer, Altoida

Brad Gescheider, Chief Commercial Officer, Woebot Health

Hillel Lehmann, Vice President, Transformation, Nestle Health Science

Dave Matthews, Chief Growth Officer, BrightInsight

10:50am

Morning Refreshments & Networking

Track 1 - Ballroom ABC

Enabling DTx

Chaired by Matthias Zenker, Chief Medical Solutions Officer, GAIA AG

11:20am Presentation: Beyond RCT and RWE: Leveraging the Power of Research Across the Digital Therapeutic Lifecycle

- Most DTx companies are aware of the biggest, most time-consuming and expensive types of research studies: the pivotal RCT needed for FDA clearance, and the RWE/HEOR needed for reimbursement.
- This presentation will argue that research can do so much more

Track 2 - Ballroom D

DTx in Action

Chaired by Mattew Stoudt, Chief Executive Officer, AppliedVR

11:20am Digital Therapeutics is Ready For Take-Off in Asia: Regulatory & Reimbursement Updates

- Inaugural DTx Asia Recap
- Regulatory Updates: How are APAC countries regulating digital therapeutics?
- Reimbursement Updates: South Korea, Japan, and China how are single-payers reimbursing DTx?

for DTx companies, including: informing product design and improvement, developing robust intended use guidelines to drive better outcomes, and enhancing overall scientific credibility for the company.

Acacia Parks, Digital Health Advisor & Fractional Chief Science Officer, Found

- Insights into navigating the regulatory landscape in Korea
- How is WELT developing personalized digital therapeutics leveraging digital biomarkers, and what are South Korean regulators' and payers' views on this?

Danny Kim, Head of WELT USA, WELT

11:45am Panel Discussion: The Current State of DTx from the Eyes of a Digital Health Investor

- An overview of the current landscape of digital therapeutics from the perspective of an investor
- What do investors want to see from digital therapeutic companies before they can part with their cash?
- How is inflation affecting investment?
- How can investors rope in fund strategies for founders?
- Is it accurate to compare the large influx in funding off the back of COVID-19 to now?
- What have we learnt from digital health exits over the past two years?
- How is the changing environment affecting funding for early stage start-ups and late stage start-ups?
- Where do we go from here?

Moderator: Scott Barclay, Managing Director, Insight Partners Galym Imanbayev, Partner, Lightspeed Venture Partners Amanda Way, Principal, Jazz Venture Partners David Kim, Managing Director, DigiTx Partners

11:45am Fireside Chat: The Role of Digital Health to Alleviate Oncology Patients Unmet Needs

Cancer is scary. Patients and their caregivers navigating the emotional, physical and clinical oncology journey often feel isolated, frustrated and confused. This panel discussion will explore the role of digital tools to provide guidance and support throughout the oncology patient journey.

- What are the biggest unmet needs along the oncology patient journey?
- How can digital approaches address the unmet needs?
- What other stakeholders need to collaborate to improve the patient experience in oncology?
- How can integrating mental health into the patient journey in oncology serve as a "magic pill" for patients?
- What techniques are proving effective in isolation, but have not been scaled to more patients?

Andrzej Jonczyk, US CEO, Prosoma John Kutz, Managing Director, EVERSANA Julia Eaton, Senior Director, Commercial Strategy Leader, Genentech

Lunch and Networking

2:00pm Fireside Chat: The Product, Provider and Patient - Provider Experiences with Using and Prescribing DTx

- Providing patient feedback and first-hand experiences of clinicians in providing patient care using digital therapeutic products
- Demonstrating uses of partnerships and a precision care model to shorten the gap between need and care for the patient
- Understanding levels of adoption and incorporating digital therapeutics tools and digital communities for patients post-triage
- Increasing clinician engagement and key factors that allow for providers to incorporate digital therapeutics into their workflow

Dilek Barlow, Vice President of Product Strategy, Twill
Alyssa Dietz, Senior Director, Precision Care Strategy, Twill
Patient of Twill

2:00pm Presentation (Case Study): How Oura Partnered with Natural Cycles to Power the World's First Birth Control App With Input from a Wearable

A practical discussion about how Natural Cycles leveraged the Oura Ring to power its FDA cleared birth control app

- What advantages did Natural Cycles see from integrating a wearable into their digital therapeutic? Why Oura specifically?
- How did the companies validate the integration would work from both scientific and commercial perspectives?
- How did the companies leverage different marketing channels to drive awareness and adoption?
- What challenges did we encounter and how did the companies overcome them?
- Lessons for other digital therapeutic solutions

Geoff Wylde, General Manager for Business & Head of Business Development, Oura

Courtney Jerden, Head of Supply Chain & Logistics, Business Development Leader, Natural Cycles

2:30pm Panel Discussion: How Can DTx Leverage Telehealth?

- The evolution of telehealth and telemedicine since the Covid-19 public health emergency
- Use of telehealth for prescription of PDTs, patient acquisition and patient support within a DTx platform
- Which commercial models and therapeutic areas in DTx would benefit most from telehealth?
- Lessons learnt from adoption of telehealth for patient acquisition and prescription in pharma

2:30pm Fireside Chat: The Role of DTx in Autism, Neurodevelopment and Value Based Care

- From a clinician's perspective, how can DTx be most effectively used alongside other therapies in autism (medical testing and treatment, behavioral therapy, developmental therapies, family support)?
- How can DTx companies work effectively with healthcare providers? (across both research and market launch)
- What are reimbursement mechanisms (including Value Based Care) that allow DTx to be used by healthcare providers at scale?

Moderator: Matthias Zenker, Chief Medical Solutions Officer, GAIA AG
Joe Perekupka, Chief Executive Officer, Freespira
Scott Snyder, Chief Digital Officer, EVERSANA
Jamie Meyerson, Vice President, Provider Operations, Mayen Clinic

Vijay Ravindran, Chief Executive Officer, Floreo Neil Hattangadi, Chief Executive Officer, Cortica

3:10pm

Afternoon Refreshments & Networking

3:50pm Presentation: Building the Digital Patient Journey

- Getting the patients to use your product is one thing, but we must implement strategy to increase retention
- What is a digital health community?
- What models do companies have in place to increase adherence?

Amanda Woodward, Insights Manager, Strategy, Twill

4:15pm Panel Discussion: Increasing User Engagement - How to Raise the Patient's Hand?

- Why are patient's apprehensive about using digital health products and how can we address this?
- What grabs a patient's attention?
- Does cultural and socio-economic backgrounds impact patient engagement of DTx products?
- How are companies planning to increase user awareness and education of digital health?
- Which business strategies are showing the most success and retention?

Moderator: Elise Vierra, Chief Creative Officer, Limbix

Lani Hessen, VP of Patient Access, Digital Therapeutics Alliance

Ricky Choi, Head of Digital Health, Samsung

Kristin Wynholds, Chief Product Officer, Better Therapeutics

Megan Jones Bell, Clinical Director, Consumer and Mental Health, Google

4:55pm Chairs Closing Remarks

Matthias Zenker, Chief Medical Solutions Officer, GAIA AG
5:00pm Drinks Reception
6:00pm Close of DTx West 2023 Day 2

Conference Day 3: Friday, 24th February, 2023

9:00am Chair Opening Remarks & Setting the Scene

Joe Perekupka, Chief Executive Officer, Freespira

9:10am Keynote Panel Discussion: Combining Human and Digital Therapeutics to Reimagine Healthcare

- Exploring a hybrid model for healthcare integrating both Digital and Human Therapeutics
- How can we better educate providers on the benefits of implementing digital into their standard of care?
- Where does DTx fit in the evolving healthcare workflow?
- Are clinicians being replaced by digital medicine?
- What key steps need to be taken before we are effectively utilizing a hybrid model of healthcare?

Moderator: Chan Yoon, Founder & CEO, EverEx
Benjamin Alouf, Chief Medical Officer, Limbix
Santosh Mohan, Vice President of Digital, Moffitt Cancer Center
Daniel Emina, Associate Medical Director, Amen Clinics Inc.
Sara Sarkey, Vice President of Neuroscience & Vaccines, Takeda

9:50am Presentation: Digital Health Strategy and Total Care Ecosystem in Pharma

- Digital Health strategy and concept of Total Care Ecosystem in Japanese pharma, Daiichi Sankyo.
- Significance of co-development with health tech ventures from the early stage.
- How we can create Total Care Ecosystem by Japanese pharma

Shin Nakajima, Senior Director, Daiichi Sankyo

10:15am

Morning Refreshments & Networking

10:45am Presentation: Our Experience with Nationwide Reimbursement of Digital Therapeutics in Germany

- Regulatory innovation: How DiGA approval combines market access, nationwide reimbursement and price setting
- Not all PDTx are created equal: Product-specific differences in patient and prescriber adoption
- What's next? Moving from point solution provider to blended care platform

Hannes Klopper, Chief Executive Officer & Co-Founder, HelloBetter

11:10am Presentation: How the Access Crisis in Pediatric Mental Health is Straining Families

- Addressing the increased need for pediatric mental health care and decreasing demand.
- What are the core building blocks for digital health solutions?
- What does success in a post-covid world look like for both families and people who care (providers, payors, employers)?

Jason Kahn, Chief Science Officer & Co-Founder, Mightier

11:35am Presentation: The Dynamic Duo: App-Enabled Precision Engagement Meets Population Health Management

Divya Shankar, Director of Program Management, Glooko

12:00pm Panel Discussion: What's Next for DTx?

- After three days of talking about everything digital therapeutics, would you say that today we are where we expected to be a year ago?
- How do we expect the discussions around Adoption, Reimbursement, Regulation, etc. to change by the next DTx West?
- How can we do better as an industry?
- What are the greatest challenges that the industry must tackle before continuing on an upward trend to success?
- How can we do better as an industry?
- What is each panelist's final piece of advice for the audience?

Moderator: Yuri Maricich, Chief Medical Officer, Pear Therapeutics Frank Karbe, Chief Executive Officer, Better Therapeutics Shaheen Lakhan, Chief Medical Officer, Click Therapeutics Arun Gupta, Chief Executive Officer, Big Health

12:50pm Chairs Closing Remarks

Joe Perekupka, Chief Executive Officer, Freespira

1:00pm

Close of DTx West 2023