



DTxDM EAST

Day 1. Tuesday, September 25th 2018

8:00 Registration, Breakfast & Networking

Defining the Commercial Opportunities for Digital Therapeutics & Digital Medicine

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

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

Edward Cox, Chief Executive Officer, [Dthera Sciences](#)

9:15 Fireside Chat: **Pear Therapeutics and Novartis**

An exclusive look into the partnership on everyone's minds. This is an unprecedented opportunity to discover more about this groundbreaking collaboration, by hearing a first hand account from the leading executives on both sides of the partnership. This fireside chat will be shaped around key themes, including:

- Understand how the Pear-Novartis collaboration came to be
- What are the unique challenges facing Novartis when trying to integrate digital therapy methodologies?
- Once a partnership is established, how is this operationalized as a commercial product to sell - is there a need for a new division within Pharma to be created?
- How do Pear currently view the day-to-day working relationship with Novartis?
- Do we expect to see more Pharmaceutical companies following Novartis' lead?

Yuri Maricich, Chief Medical Officer & Head of Clinical Development, [Pear Therapeutics](#)

Joris van Dam, Executive Director, Head of Digital Therapeutics, [Novartis](#)

9:45 Opportunities and Challenges in using the Specialty Pharmacy Model to Increase Adherence, Outcomes, and Produce RWE for Digital Therapeutics

- The number of precision medicines and specialty type therapies currently in development has risen dramatically, as is the development of companion digital therapeutics to clinical treatments.
- On the commercial side of the house the number of specialty therapy brand teams who are looking to implement solutions to better assess new patients for risk and deploy personalized digital care is rising. In

the middle is a no man's land between commercial and clinical where the evidence produced in RCT's is not representative of real world value.

- The specialty pharmacy distribution model is unique in its inherent high touch with prescribers and patients to better manage a brands success utilizing digital therapeutics and patient engagement, consequently it is also a promising model to produce RWE for payers to prove the outcome based value in a digital therapeutic.
- In this presentation we will explore the opportunities and challenges for deploying digital therapeutics with brands and specialty pharmacies, and the “glue” that is required to be successful.

Marc Duey, President and Founder, [ProMetrics](#)

Kyle Flickinger, Executive Director, SPEED, [ProMetrics](#)

Jeff Elton, Chief Executive Officer, [Concerto Health AI](#)

10:10 Keynote Panel and Open Q&A: **Pioneers Perspective** - Deciphering the Commercial Opportunities for Digital Therapeutics and Digital Medicine

This focused session allows attendees to discuss the different models of commercialization for Digital Therapeutics and Digital Medicine. As this industry continues to diversify, clear and detailed knowledge of the routes to market is paramount for all those interested and invested in this space. Tap into the minds of the leading pioneers within this space through an open forum:

- Since DTxDM West, how have our goals evolved as an industry?
- Digital Therapeutics vs. Digital Medicine - what are the commonalities and differences now?
- How have your conversations with external players such as pharma and payers changed over this year?
- Reimbursement for Digital Therapeutics/Medicine: What opportunities are available?
- Which companies have gone public this year, and when is the right time to do so?
- From a commercial perspective, what needs to happen for this industry to continue to advance?
- With such a gathering of pioneers at this summit, what does the panel hope to achieve in the next 2 days?

Adam Kaufman, Chief Executive Officer, [Canary Health](#)

Kevin McRaith, Chief Executive Officer, [WellDoc](#)

Pierre Laurent, Chief Executive Officer, [Voluntis](#)

Eddie Martucci, Chief Executive Officer, [Akili Interactive](#)

10:50

Morning Refreshments & Networking

Interactive Workshop Sessions

During these intimate breakout sessions, attendees will address some of the key themes surrounding Digital Therapeutics and Digital Medicine. Use these workshops as a chance to get the answers to your burning questions around definitions, regulation and reimbursement.

The topics for the workshops will run twice so that attendees can attend two sessions and get maximum value from these crucial discussions! You are spoilt for choice!

11:20 Workshop Session A:

Workshop 1A: Digital Therapeutics and Digital Medicine 101

- How are Digital Therapeutics and Digital Medicine currently being perceived outside the industry?
- What is the ceiling potential of this industry?
- How is the healthcare system going to need to adapt to fully take advantage of these technologies and approaches?

Jeffrey Abraham, VP, Market Access & Trade, **Akili Interactive Labs, Inc.**

Workshop 2A: Understanding the Regulatory Pathways

- What are the different regulatory classifications used in this space?
- How have the FDA become more receptive to conversations around digital health?
- What innovative regulatory pathways are currently being explored?
- What has been the impact of the FDA Pre-Cert Program work?

David Amor, VP, Quality & Regulatory Affairs, **Pear Therapeutics**

Workshop 3A: Applying Novel Evidence Generation Techniques to Digital Therapeutics Development

Digital Therapeutics (DTx) companies have been successful at generating a growing evidence base, yet much can still be done to leverage new techniques to develop more persuasive evidence faster and more economically. Learn more about how Digital Study Operations and Connected Data Approaches can go from code to commercial faster.

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- New models for Digital Study Operations such as Virtual Trials can improve the efficiency of current RCTs, while new Connected Data Approaches to data collection such as Pragmatic Studies, Enriched Studies, and Evidence Platforms may help to prove not only efficacy but the effectiveness of digital therapeutics products
- Questions remain as to how key regulatory, market access, and uptake stakeholders should assess evidence of effectiveness, particularly that which leverages real world data, creating an opportunity for the industry to engage these stakeholders to create mutually agreed evidence guidelines

-**Gordon Cummins**, Principal, Real World & Analytics Solutions, **IQVIA**

-**Brian Clancy**, Co-Lead, AppScript by IQVIA, **IQVIA**

-**Brian Kelly**, President, Payer and Provider Solutions, **IQVIA**

-**Jenn Millard**, Real-World Enterprise Solutions Center of Excellence Team Lead, U.S., **IQVIA**

Workshop 1B: Digital Therapeutics and Digital Medicine 101

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Digging Deeper: Clinical Evidence Showcase

Observe as some of the leading companies in this space showcase their robust clinical data for your eyes only. With 20 minute presentations, questions will be held off until speakers reconvene on the Q&A panel that follows...let's really *dig deep* and tackle the critical questions surrounding clinical validation for Digital Therapeutics and Digital Medicine.

1:50 **Clinical Case Study 1:** Behaviors & Chronic Disease

- Clinical Trial results will be showcased that explore Digital Therapeutics being used to help people quit smoking and modify other behaviors that contribute to (or exacerbate) chronic disease
- Findings from two Case Studies will be shared that explore how Digital Therapeutics are being used in a Real-World Setting

Jo Masterson, Chief Operating Officer, [2Morrow, Inc.](#)

2:10 **Clinical Case Study 2:** Autism

- A look at the latest results: How are Digital Therapeutics and diagnostics improving the clinical results for patients with autism?
- Health outcomes will be analyzed to demonstrate successes and lessons learned

Sharief Taraman, MD, Chief Medical Officer / Chief of Neurology, [Cognoa / Children's Hospital of Orange County](#)

2:30 **Clinical Case Study 3:** Chronic Back Pain

- A look at how Digital Therapeutics can significantly improve the quality of care for patients with chronic back pain
- Results will be showcased, and the strengths and weaknesses of different clinical designs will be discussed

Konstantin Mehl, Chief Executive Officer, [Kaia Health](#)

2:50 Interactive Panel and Open Q&A: **Innovative Clinical Validation Models** - What Are They and How Are They Being Developed?

This session will explore what sets Digital Therapeutics apart from other health and wellness apps, and demonstrate the importance of clinical evidence. Discussions around innovative clinical validation models are crucial for the advancement of Digital Therapeutics and Digital Medicines; so this is a valuable opportunity to tap into the minds of the experts through open Q&A:

- Why is clinical validation so imperative to drive the success of this nascent industry?
- What are Digital Therapeutic companies doing differently in comparison to traditional trials?
- What will it take for Digital Therapeutic companies to succeed when publishing clinical evidence?
- Through our scientific understanding of Digital Therapeutics, what diseases should be targeted?
- How are pharma viewing the clinical validation being developed by Digital Therapeutics?
- How are payers, providers and physicians viewing the clinical validation being developed by Digital Therapeutics?

Brandon Masterson, Chief Executive Officer, [2Morrow, Inc.](#)
Brent Vaughan, Chief Executive Officer, [Cognoa, Inc.](#)
Konstantin Mehl, Chief Executive Officer, [Kaia Health](#)
Peter Hames, Co-Founder & Chief Executive Officer, [Big Health](#)

3:30

Afternoon Refreshments & Networking

Stakeholder Perspectives: Pharma & Investors

4:00 Interactive Panel and Open Q&A: Analyzing **Pharma's Short-Term and Long-Term Goals** for Digital Therapeutics and Digital Medicine.

This session will cover why some Digital Therapeutics and Digital Medicine companies are choosing to collaborate with Pharmaceutical companies; and vice versa. Hear from the experts with first-hand experience of these new established partnerships, as well how this nascent industry is currently being viewed by pharma. This session will allow attendees to tap into the pharma perspective and pose important questions to speakers:

- How will pharma companies benefit from a Digital Therapeutic/Medicine collaboration?
- What are pharma companies going to offer to the Digital Therapeutics/Medicine industry?
- How do pharma view the current partnering models in this space?
- Are pharma more receptive to these ideas if they fit with their traditional R&D and commercial strategies?
- Once a partnership is established, how are digital products going to be operationalized as a commercial product to sell?
- How will pharma organize the cross-department development work - is there a need for a new internal division within pharma to be created?

Melinda Decker, Head of Oncology & Immuno-Oncology, Intelligent Pharmaceuticals, [AstraZeneca](#)

Jeff Mathers, Senior Director, Software Engineering & Emerging Technology, [Johnson & Johnson Technology](#)

Joris van Dam, Executive Director, Head of Digital Therapeutics, [Novartis](#)

Bozidar Jovicevic, Vice President, Global Head of Digital Medicines, [Sanofi](#)

Jim O'Donoghue, President, [S3 Connected Health](#)

4:40 Interactive Panel & Open Q&A: What is the Current **Investor Sentiment** towards Digital Therapeutics & Digital Medicine?

This session will explore the current investment landscape for Digital Therapeutics and Digital Medicines. With leading investors on stage, understand what the current market sentiment is towards digital companies.

Digital Therapeutics and Digital Medicine have huge potential but much needs to be discussed and realized for them to deliver significant ROI. Get under the skin of the investor thinking in this space:

- How do investors view the current Digital Therapeutic and Digital Medicine landscape?
- What are investors single biggest concern about Digital Therapeutics and Digital Medicine right now?
- How can Digital Therapeutic/Medicine companies successfully raise enough capital?
- What do investors want to see from these companies during early discussions?
- What can this industry learn from others when it comes to delivering its commercial potential?
- Paths to exit - when is it likely companies will go public and what can they expect?
- What are the current exit strategies that are being discussed?

Ruchita Sinha, Senior Director of Investments, [Sanofi Ventures](#)

Sasha Said, Growth Equity Investor, [Leerink Transformation Partners](#)

John Spinale, General Partner, [Jazz Venture Partners](#)

Cris de Luca, Global Director, Digital Innovation, [Johnson & Johnson Innovation](#)

Digital Showcase: Emerging Technology & Strategies

These quick-fire presentations are designed to showcase some of the latest creations within the Digital Medicine and Tech space. Witness for yourselves some of the remarkable innovations that are propelling this industry into unprecedented medical territory - peer into the future and prepare to be amazed!

5:20 Disruptive Content in Rare Disease & Digital Medicine

- Hear how Patrick, a successful NYC actor who lost his brother to hemophilia, has dedicated his life to reaching out to other young people with rare, chronic and life threatening diseases.
- Discover how he built a digital content company aimed exclusively at taking complex medical concepts and outreach challenges, and turning them into watchable, sharable, impactful content.
- A look at three examples of this content, and why they work at reaching their intended demos.

Patrick James Lynch, CEO & Co-Founder, [BelieveLTD](#)

5:30 Neurotech in Focus: Applying Digital Therapeutics and Wearable Technology to Chronic Disease

- Discover how recent advances in neurotechnology are transforming the lives of people living with chronic diseases through wearable therapeutic devices
- A look at how Neurometrix is on a mission to improve health through digital diagnosis and treatment

Frank McGillin, Chief Commercial Officer, [Neurometrix](#)

5:40 **Drinks Reception**

After an intense day of learning and discussions, let your hair down with your peers over drinks and canapés. Use this informal session as you like. Make some final connections, catch-up on discussions earlier in the day or converse about something completely unrelated! This will certainly be a well-earned drink or two or more...

Day 2. Wednesday, September 26th 2018

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?

Joel Sangerman, Chief Commercial Officer, [Click Therapeutics](#)

Decisive Debates: Payer, Healthcare System & FDA Incentives

9:10 Interactive Panel and Open Q&A: **Payer Perspective** - An Honest look at Digital Therapeutics and Digital Medicine

This crucial panel session will detail the current reimbursement and coverage landscape for Digital Therapeutics and Digital Medicine. As validated digital interventions continue to make it to market via a variety of business models, plenty of discussion remains around how payers will adopt these on a large scale. Often described as the biggest challenge facing this industry, this session will allow attendees to pose question to leading payers:

- Is there a general consensus amongst payers towards these products and if so, what is it?
- What experiences can leading payers share about their current work with the industry?
- What should digital companies be considering before approaching payers with their plans?
- How should Digital Therapeutic/Medicine companies approach pricing, given reimbursement goals?
- What are the current thoughts on pay-for-performance vs. pay per-member-per-month models?
- How do we “operationalise” these payment models in the real world?

Everett Crosland, Vice President, Market Access, Reimbursement & Government Affairs, [Pear Therapeutics](#)

Debra Reisenthel, Chief Executive Officer, [Palo Alto Health Sciences](#)

Steve Cutts, Vice President, Pharmacy Services and Clinical Strategy, [Magellan Rx Management](#)

Eileen Rodgers, Director of VITAL Program, [Highmark Health](#)

Tim Pearce, Manager, Market Research and Strategy, [Stella / Blue Cross and Blue Shield of Minnesota](#)

10.00 Interactive Panel and Open Q&A: **Building the Ecosystem** - Frontline Stakeholder Perspectives

This crucial session will be led by key representatives from major stakeholder groups within the healthcare industry. Digital Therapeutics and Digital Medicine hold huge promise but the healthcare system is complex and there will need to be flexibility from both sides for this potential to be realized. Gain insight into:

- The current perspective of the frontliners: Providers, Physicians and Patients
- Understand how we can advance provider adoption - is the FDA route the one Physicians will trust?
- Will Digital Therapeutics/Medicine produce too much data for physicians and healthcare to handle?
- What do Digital Therapeutic/Medicine companies need to do to demonstrate value?
- Are Digital Therapeutic companies prepared to meet the healthcare industries privacy regulations?
- What needs to be adapted in the current healthcare system to increase the application of these technologies?

Kathryn Salisbury, Executive Vice President of Strategy and Business Development, [Vibrant Emotional Health \(Formerly MHA-NYC\)](#)

Seth Feuerstein, Chief Innovation Officer & Chief Medical Officer, Medical & Digital Innovation, [Magellan Health](#)

Gregory Dodell, MD, FACE, President of Central Park Endocrinology, Assistant Clinical Professor of Endocrinology, Diabetes and Bone Disease, [The Mount Sinai Hospital](#)
Joseph Glass, Assistant Investigator, [Kaiser Permanente Washington Health Research Institute](#)

10:45

Morning Refreshments & Networking

11:15: **FDA Presentation** Plus Interactive Q&A Session [Remote Session]:

- The latest updates from the FDA Pre-Cert Program for Digital Health and Digital Therapeutics in particular
- Discussion around what impact the FDA Pre-Cert Program has had on the outlook for Digital Therapeutics organizations
- Outlining the key differentiators between Digital Therapeutics and other digital health products in the Pre-Cert program and other Digital Health Action Plan tasks, like premarket review
- Regulatory challenges surrounding Digital Therapeutics as a subset of Digital Health

Bakul Patel, Associate Centre Director for Digital Health, [FDA](#)

Digging Deeper: Deciphering the Business Models

Hear from some of the pioneers in this space, all implementing successful yet differing business models to get their products to market. Similar to the clinical evidence showcase yesterday, questions will be held off until speakers reconvene on the Q&A panel that follows lunch, allowing enough time to dig deeper into these go-to-market strategies.

11:45 Case Study 1: **Presentation by AppliedVR**

- A look at the key opportunities and challenges associated with commercializing your product to health care providers
- Understand how this business model is a viable go-to-market strategy
- Discussion will center around use-cases of how virtual reality and immersive tech can drive positive behaviour change, adding value to multiple healthcare disciplines

Matthew Stoudt, Chief Executive Officer, [AppliedVR](#)

12:05 Case Study 2: **Presentation by Click Therapeutics**

- Understand how this established business model has been improving the well-being and health of users for years
- A look at the challenges associated with getting these products adopted by large organisations
- Discussion will focus on the relevance of regulatory clearance for these products

Joel Sangerman, Chief Commercial Officer, [Click Therapeutics](#)

12:25 Case Study 3: **Presentation by Litesprite**

- Understand how Litesprite commercializes its award-winning product to patients providers & has established a new business model
- Discussion will focus on the appropriate use of CPT codes for these products

Swatee Surve, Founder & Chief Executive Officer, [Litesprite](#)

12:45 Case Study 4: **Presentation by Better Therapeutics**

- Understand how “prescription digital therapeutics” are breaking new ground in the healthcare sector
- Discussion will focus on the regulatory pathway that is being carved out by these pioneering companies
- Case studies describing the long-term vision for this new healthcare paradigm will be analysed

Kevin Appelbaum, Chief Executive Officer, [Better Therapeutics](#)

1:05

Networking Lunch

Business Models and Looking Ahead

2:05 Closing Panel and Open Q&A: **Leading Business Models** and the **Future of the Industry**

This closing panel session will allow attendees to tap into some of the leading commercial minds in this space. In an industry with a mix of innovative business models, understanding the challenges and opportunities associated with the leading go-to-market strategies is paramount. This session will also be a chance to wrap-up the conversations and ask any final questions, as we look ahead to the future of the industry:

- What are the current business models being pursued with Digital Therapeutics and Digital Medicines?
- Prescription Digital Therapeutics vs. Targeting employers vs. Targeting providers - what are the defining characteristics of each?
- Moving forward, how are emerging partnership models influencing commercial opportunities?
- Looking ahead, what does the reimbursement landscape look like for Digital Therapeutics and Digital Medicine?
- How much capital are Digital Therapeutic and Digital Medicine companies generating?
- What needs to happen now for Digital Therapeutics and Digital Medicine to reach their full potential?
- How do goals of good medical outcomes, high provider demand, and fair payer coverage get achieved?
- How are Digital Therapeutics and Digital Medicine expanding globally?

Swatee Surve, Founder & Chief Executive Officer, [Litesprite](#)

Kevin Appelbaum, Chief Executive Officer, [Better Therapeutics](#)

Matthew Stoudt, Chief Executive Officer, [AppliedVR](#)

Alex Waldron, Chief Commercial Officer, [Pear Therapeutics](#)

2:55 Chairman's Summary

- What have been the key lessons learnt from the DTxDM East 2018?
- What are we expecting the industry to look like at DTxDM West 2019?

Joel Sangerman, Chief Commercial Officer, [Click Therapeutics](#)

3:05 Close of DTxDM East 2018