Draft Agenda:

EVIDENCE BASED DIGITAL HEALTH IN PHARMA

Boston, MA
May 21st-22nd 2024

Conference Day 1
8:00am **Registration, Breakfast and Networking**
Standards of Evidence-Based Digital Health in Pharma and Regulatory Position - Where Are We Now?
9:00am **Chairs Opening Remarks and Setting the Scene**
9:10am **Keynote Presentation: Navigating the Digital Health Landscape in Pharma: Trends, Challenges, and Evidence-Based Progress** This presentation, led by an industry expert, will kick off the day by establishing the foundation for evidence-based digital health in pharma. It will delve into the ongoing trends and challenges encountered by the pharmaceutical sector when adopting digital health technologies, and offer insights into how we can utilize evidence to progress the industry. ● Define what evidence-based digital health means to the pharma industry, and explore the latest trends and strategies in pharma's adoption of digital health technologies. ● Discuss the key challenges and barriers faced by pharma in effectively integrating digital health solutions into their practices. ● Examine how evidence-based approaches can drive progress and innovation within the pharmaceutical sector, ultimately benefiting patient outcomes and the industry as a whole.

Celine Marquez, Global Medical Director, Digital Health Technologies, **Genentech**

9:35am **Keynote Panel Discussion: Integrating Digital Health Innovation with Corporate Strategies and Operating Models**

'Digital health' encompasses a broad spectrum of technologies, with many more than just the popular subset of digital therapeutics, and considerations of potential revenue, cost, and chance of success must be evaluated when deciding which novel digital solutions to develop. In this keynote panel discussion, we engage with top digital and technology executives at the forefront of the pharmaceutical industry to gain insights into the strategies and approaches used when evaluating digital health technologies for adoption.

- How do you prioritize digital health initiatives within your organization, and what key factors influence your decision-making process?
- What evidence needs to be considered when evaluating the chance of success for novel digital health solutions in the pharmaceutical industry?
- How do you assess whether a novel digital health technology aligns effectively with the unique needs and objectives of your organization?
- How are pharmaceutical companies adapting their operating models to effectively incorporate digital health technologies and data-driven approaches into their research, development, and commercialization processes?
- What are the biggest challenges encountered in implementing digital health strategies, and how can we overcome these looking forward?

Moderator: **Celine Marquez**, Global Medical Director, Digital Health Technologies, **Genentech**
Meri Kay Scott, Associate VP, Digital Health R&D – Clinical Operations, **Eli Lilly**
Davide Ricci, US Vice President, SaMD, **Novo Nordisk**

10:20am **Morning Break, Refreshments & Networking**

11:10am **Case Study: Assessment of Wearables**

- Assess the current level of adoption of wearable technologies within the pharmaceutical industry.
- Explore how wearables are being utilized in clinical trials and their influence on data collection, patient monitoring, and trial efficiency.
- Discuss the challenges and hurdles the pharma industry faces in fully leveraging wearables, and explore potential future directions and innovations for research, development, and patient care strategies.

Kapil Parakh, Senior Medical Lead, **Google**

11:35am **Presentation: Update from the Digital Health Center of Excellence**

- An overview of the Center for Device and Radiological Health (CDRH) Digital Health Center of Excellence (DHCoE) and its mission to promote a patient-centered approach with a focus on health equity.
- An outline of DHCoE areas of technical interest with a particular focus on AI/ML-enabled medical devices.
- A view on the use of digital health technologies in clinical investigations.

John Nicol, Digital Health Specialist, Digital Health Center of Excellence, **FDA**

12:00pm **Panel Discussion: Innovation Meets Regulation: The Evolving Digital Health Landscape in Pharma**

As the regulatory landscape for digital health in pharma undergoes rapid transformation, this panel will shed light on the latest regulatory developments and their implications. Participants will engage in a deep dive into the specific regulatory hurdles and compliance strategies essential for advancing evidence-based digital health solutions within the pharmaceutical sector.

- What does the current regulatory landscape look like for evidence-based digital health technologies?
- How can regulatory agencies and pharma companies better align to ensure the safety and efficacy of digital health solutions?
- What strategies can pharma employ to streamline the regulatory approval process for digital health technologies and promote an open framework for interoperability?
- How can regulators adapt to the rapid pace of technological innovation in healthcare, and what steps can pharma take to bridge this gap for start-ups and biotechs?

Moderator: **Amir Lahav**, Strategic Advisor, **Pharma & MedTech**
Lori Roadcap, Senior Director, Global Regulatory Strategy and Policy for Precision Medicine, Diagnostics and Digital Health, **Bristol Myers Squibb**
Prasad Peri, AVP Regulatory Affairs Connected Delivery, Devices, and Digital Health, **Eli Lilly**
Sarah Fairfield, Associate Director Regulatory Affairs, **AbbVie**

12:45pm **Lunch and Networking**

Using Evidence to Inform Pharma and Payer Decision Making in Digital Health Adoption and Application

2:00pm **Panel Discussion: Generating and Assessing Clinical and Real-World Evidence for Digital Health Adoption in Pharma**

In an era marked by rapid technological advancements and the proliferation of digital health solutions, the pharmaceutical industry is increasingly relying on evidence from clinical data and real-world data (RWD) to inform decision-making. This panel will delve into the critical considerations and best practices for assessing evidence when adopting digital health technologies in pharma, aiming to strike a balance between innovation and rigorous evaluation.

- How do the strengths and limitations of clinical evidence compare to those of real-world evidence (RWE) when assessing the effectiveness and safety of digital health technologies in pharmaceutical applications?
- What criteria should be used to assess the quality and strength of evidence when evaluating digital health technologies for pharmaceutical applications?
- What ethical and privacy considerations should be addressed when collecting, storing, and utilizing patient data in digital health adoption, especially in a global context with varying regulations?
- In what ways can patient-reported outcomes and experiences be integrated into evidence assessment, and what impact does patient engagement have on the evaluation process?

Moderator: **Sarah Valentine**, Partnerships Lead, **Digital Medicine Society (DiMe)**
Kelly Zou, Head of Global Medical Analytics and Real World Evidence, **Viatris**
Viviktha Ramesh, Clinical and Evidence Expert, **Roche Information Solutions**
Jay Trudeau, Senior Director, Patient-Focused Endpoints and Measurement, **Eli Lilly**

2:45pm **Fireside Chat: HEOR Considerations from a Payer Perspective**

In the realm of digital health, understanding Health Economics and Outcomes Research (HEOR) is paramount as it helps quantify the value and impact of digital health solutions on patient outcomes and healthcare costs. Join our panel discussion to explore how payers leverage HEOR considerations to make informed decisions about which digital health solutions to include in their coverage plans, ensuring optimal healthcare resource allocation.

- How does HEOR data contribute to assessing the value of digital health solutions in terms of patient outcomes and healthcare expenditures?
- What specific HEOR metrics do payers prioritize when evaluating and selecting digital health interventions for coverage?
- What challenges do payers face in integrating HEOR insights into their decision-making processes, and how can these obstacles be overcome to enhance healthcare resource allocation?
- Besides HEOR considerations, what other factors and data sources do payers take into account when selecting and covering digital health interventions?
- What strategies can be implemented to better align payer expectations with pharma, regulatory, and provider groups?

Kaitlin Gately, Lead Clinical Analyst, **Point32Health**
Timothy Law, Chief Medical Officer, **Highmark**

3.20pm **Afternoon Break and Refreshments**

4:10pm **Fireside Chat: The Need for a Prescription Digital Health Pathway**

Developing a prescription pathway within the digital health industry has proven to be a challenging endeavor. In this fireside chat, we will delve into the current progress made in establishing this essential pathway, shedding light on the progress made towards passing the *Access to Prescription Digital Therapeutics* Act.

Andy Molnar, CEO, **Digital Therapeutics Alliance (DTA)**
Sara Elalamy, Founder, **Xpert Lobby LLC**

4:40pm **Panel Discussion: Strategies for Adopting Digital Health: Build, Buy, or Partner?**

In today's rapidly evolving healthcare landscape, pharmaceutical companies must explore various pathways to adopt digital health technologies effectively. This panel will delve into the approaches of building digital solutions in-house, acquiring them externally, or forming strategic partnerships to harness the potential of digital health in pharma.

- How can pharmaceutical companies make informed decisions about developing digital health solutions internally vs seeking external partners?
- What challenges and opportunities are associated with each approach, and how can pharma organizations mitigate risks while maximizing benefits?
- What are the key considerations when evaluating potential digital health technology acquisitions or partnerships?
- In the realm of novel digital health technologies, how can we effectively discern genuine value from mere potential?
- In your experience of digital health adoption in pharma, where have you witnessed notable successes when it comes to strategies encompassing building, acquiring, or partnering?

Kaitlyn O'Connor, Partner, **Nixon Gwilt Law**
Catherine Blanchette, Global Head of Digital Innovation & Partnerships, **Sanofi**
Ofer Waks, Director, Digital Strategy and Innovation, **Pfizer**
Norah Xiao, Director Digital Health Partnership, **AstraZeneca**
Yao Zhang, Senior Director of External Innovation in Interventional Oncology, **Johnson & Johnson**

5:25pm **Chairs Closing Remarks**

5:30pm - 7:00pm **Drinks Reception**

7:00pm **Close of Day 1 of the Evidence-Based Digital Health in Pharma Summit**

Evidence-Based Digital Health in Pharma Conference Day 2

8:00am **Registration, Breakfast and Networking**

Continuing Pharma's Digital Health Journey: Integration, Patient-Centricity, Funding, and Innovative Technologies

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

Amir Lahav, Strategic Advisor, **Pharma & MedTech**

9:05am **Keynote Presentation: Pharma's Role in Facilitating the Integration of Digital Health Technologies into Healthcare Systems**

In the ever-evolving landscape of digital health, achieving a seamless integration into healthcare systems is as crucial as developing innovative and impactful digital health tools. Join our keynote presentation, led by a distinguished pharma executive, as we navigate how pharma supports the successful assimilation of digital health solutions into healthcare systems, ensuring they deliver lasting value to patients and providers alike.

- Explore the vital role that pharmaceutical companies play in facilitating the integration of digital health technologies into healthcare systems to enhance patient care and outcomes.
- Assess the strategic approaches and best practices employed by pharma to ensure the seamless assimilation of digital health technologies from development to implementation, while considering the role of evidence in these processes.
- Examine how evidence-based strategies facilitate the successful transition of digital health tools from pharma into healthcare systems.

Alex Condoleon, Chief Medical Affairs Officer of Global Medical Engagements & Impact, **Pfizer**

9:30am **Keynote Panel Discussion: A Multi-Stakeholder Perspective on Building Patient-Centric Digital Health**

At its core, our objective is to harness the transformative potential of digital health to elevate patient outcomes, so it is important to analyze if patient perspectives are considered at all levels of digital health technology development. This panel discussion will explore strategic insights into how the pharmaceutical industry can optimally embrace a patient-centric approach when implementing digital health solutions, collaborating with other stakeholder groups to ensure that patient perspectives and patient outcomes shape the future of healthcare technology.

- How can pharma use patient-generated health data (PGHD) in the development and implementation of digital health solutions?
- What collaborative approaches can stakeholder groups employ to effectively channel and act upon patient feedback?
- In what ways can we actively involve physicians in the development and refinement of digital health solutions, leveraging their clinical expertise and insights?
- What strategies can be employed to educate physicians about the benefits, risks, and functionalities of specific digital health solutions, ensuring they are well-informed advocates for their patients?
- Looking ahead, what future initiatives and trends do you foresee in the evolution of patient-centric digital health, and how can stakeholders proactively shape these developments to enhance patient outcomes?

Moderator: **Viviktha Ramesh**, Clinical and Evidence Expert, **Roche Information Solutions**
Jen Horonjeff, Co-Founder & CEO, **Savvy Cooperative**
Sarah Small, Associate Director, Patient Centricity, **Moderna**

Jennifer Joe, Global Medical Strategy & Population Health Director, **AstraZeneca**

10:15am **Morning Break, Refreshments and Networking**

11:00am **Panel Discussion: Investing in the Future: Funding Models in Digital Health**

Investment in digital health research within the pharmaceutical sector can be dynamic and challenging. In this panel discussion, led by experienced venture capital executives, we will delve into strategies for attracting investment, while also identifying crucial metrics for evaluating the return on investment in digital health projects.

- What recent trends have you observed in the investment landscape for digital health research and novel technologies?
- How do you assess the evidence and data provided by digital health innovators to inform investment decisions, and what factors contribute to your confidence in a particular project's success?
- Have you seen any impact from artificial intelligence (AI) and/or machine learning (ML) with regards to informing venture capitalists and aiding decision-making?
- How can start-ups strategically position themselves to attract investment in a rapidly evolving market?
- How do you anticipate future market trends and regulatory developments will influence investment strategies and partnerships within the pharmaceutical sector, and how can organizations proactively adapt to these changes?

Cris De Luca, Partner, Digital/AI Investments, **Sanofi Ventures**
Adam Kundzewicz, Executive Director, Venture Fund, **Boehringer Ingelheim**
Miles Gerson, Executive Investment Director & Partner, **Takeda Ventures**
Sophie Park, Managing Director - G4A Investments & Partnerships, **Bayer G4A**

11:45am **Presentation: The Roles of Artificial Intelligence and Machine Learning for Evidence Generation**

Historically, AI has found its foothold in medical imaging, but today, we are venturing into relatively new avenues and exploring its applications in medical data analysis and evidence generation. This presentation will delve into the exciting possibilities and real-world applications of AI and ML in extracting meaningful insights from vast medical datasets, contributing to evidence-based decision-making and advancing patient care.

- The impact of AI and ML on evidence generation in pharma.
- Ethical considerations and data security challenges associated with AI and ML integration in digital health.
- Opportunities for AI and ML to enhance patient engagement and outcomes.

Zhaoling Meng, AVP, Global Head Clinical Modelling & Evidence Integration, Digital and Data Sciences, **Sanofi**

12:10pm **Panel Discussion: Looking into the Future for Digital Health: Big Data Technologies and Artificial Intelligence**

In an era of rapid technological advancement, innovation in digital health technology is reshaping the healthcare landscape. Join this engaging panel to gain insights into the cutting-edge applications of big data technologies and AI

in healthcare and pharmaceuticals, and learn how these technologies are poised to revolutionize decision-making processes.

- How are big data technologies transforming the way pharma and healthcare organizations collect, analyze, and utilize patient data to enhance clinical outcomes?
- How are big data and AI technologies impacting patient engagement and empowerment in managing their own health?
- How can the integration of innovative digital health solutions into the broader healthcare ecosystem address challenges related to accessibility and affordability, ensuring that patients from diverse backgrounds can benefit from these innovative solutions?
- Considering the rapid pace of technological change, what strategies should healthcare and pharma organizations adopt to aid the integration of AI-driven architectures while addressing data privacy and security concerns?
- Where have we seen success with these innovative technologies, and how can we amplify this going forward?

Moderator: **Kelly Zou**, Head of Global Medical Analytics and Real World Evidence, **Viatris**
Charmaine Demanuele, Executive Director, Head of Quantitative Sciences for Digital Sciences & Translational Imaging, **Pfizer**
Ramya Palacholla, Director, Digital Science, **AstraZeneca**
Jessica Lipschitz, Associate Director, Digital Behavioral Health and Informatics Research Program, **Brigham and Women's Hospital**

12:55pm **Chairs Closing Remarks**

Amir Lahav, Strategic Advisor, **Pharma & MedTech**

1:00pm **Close of the Evidence-Based Digital Health for Pharma Summit**