FINAL WEEKS TO REGISTER

Cambridge Healthtech Institute's Inaugural

DIGITAL HEALTH

PHARMA CONGRESS

Leading Annual Meeting where Industry Thought Leaders Drive Innovation in Internet of Medical Things, Digital Therapeutics, Digitally-Enabled Clinical Trials, Mobile Health, and Digital Biomarkers

JUNE 17-20, 2019 • BOSTON, MA • SEAPORT WORLD TRADE CENTER

June 17

Internet of Diagnostic Things

June 18-19

Digital Health: Pharmaceutical Executive Summit

June 19-20

Digital Biomarkers: Biosensors, Wearables, and mHealth

Featured Speakers

Bernard Hamelin
VP, Evidence Generation, Sanofi

Raj Pallapothu
mHealth Global Lead, Bayer

Bert Hartog
Sr. Director, Clinical Innovation, Janssen

Mohanad Fors
Global Head, Digital Innovation Lab, Novartis

Christopher M. Hartshorn
Director, Cancer Treatment and Diagnosis, NCI

Pierre Leurent
CEO, Voluntis

Joris Van Dam
Head, Digital Therapeutics, Novartis

Mohammed Ali
Global Head, Digital Development, Boehringer Ingelheim

Michael J. Benecky
Sr. Director, Regulatory, Digital Medicine, GlaxoSmithKline

Christian Theil Lundgaard
Director, Digital Health, Novo Nordisk

Ting Shih
CEO & Founder, ClickMedix

Kamal Jethwani
Sr. Director, Pivot Labs, Harvard

Tomasz Adamusiak
Director, Digital Medicine, Pfizer

Magdalena Schoeneich
Head, Digital Accelerator, Takeda

Gergely Vértes
Solution Accelerator Lead, Wearables, UCB Pharma

David J. O'Reilly
Chief Platform Officer, Proteus Digital Health

Ida Sim
Co-Founder, Open mHealth, UCSF

Ashish Atreja
Chief Innovation Officer, Icahn School of Medicine

Part of WPW WORLD PHARMA WEEK

PharmaWeek.com/Digital-Health

Premier Sponsors

CONCEPT LIFE SCIENCES DELIVERING SCIENCE

DISCOVERY LIFE SCIENCES Science at your Service.™

Quanterix The Science of Precision Health

Sanguine specimen. data. on demand.

Premier Sponsors

Corporate Sponsors

Corporate Support Sponsors

Sponsors and Exhibitors *as of January 29, 2019*

Abcam
ABS Inc.
ACT Genomics
Agilent Technologies
Almac
AMRI
AnaBios
AntiCancer Inc.
Axion BioSystems
Benchling
Biobide, Your Zebrafish Partner
Biomodels, LLC
Biomomentum
Biopticon
BlueCatBio
BrainXell
Cellecta, Inc.
CHELATEC
Chemical Computing Group
Chemotargets
Concept Life Sciences
Domainex Limited
Exemplar Genetics
FUJIFILM Diosynth Biotechnologies
Hamamatsu Corporation
Histalim
HistoTox Labs
Hopstem Biotechnology
Invivoscribe
Linacre House
Lipotype GmbH
Lonza
Metabolon, Inc.
Miltenyi Biotec
MIMETAS
MOLECUBES
MolecularMD
MRM Proteomics Inc.
Ncardia
Neucyte
NeuroScience Associates, Inc.
Neurotar Ltd
Novabiosis
Nuvisan
OcellO
Olink Proteomics
Olympus
OmicScouts
ONI
PBL Assay Science
Peira Bvba
PharmaLegacy
ProImmune Inc.
ProteoGenex, Inc.
Proteome Sciences Plc
PsychoGenics Inc.
Quansys
Quanterix Corporation
Ricoh
Sekisui XenoTech
Sengenics
SeraCare Life Sciences, Inc.
Sofia Bio
SRI International
STEMCELL Technologies
StemEmpress
StemoniX
StudyLog
SynVivo Inc.
TaConic Bioscience
Takara Bio USA
TetraGenetics
The Jackson Laboratory
Toxikon
Toyo Gosei
Trans-Hit Biomarkers
Ultivue
ViQi
ZeClinics

FOR MORE INFORMATION, PLEASE CONTACT:

Companies A-K:

Rod Eymael
Manager, Business Development
781-247-6286
reymael@healthtech.com

Companies L-Z:

Joseph Vacca, M.S.
Director, Business Development
781-972-5431
jvacca@healthtech.com

Cambridge Healthtech Institute's Inaugural

Internet of Diagnostic Things*

Connected Diagnostics: IoT, Sensors, Wearables, and Smartphones Bring Point-of-Care Testing to the Patient

**Separate registration required*

JUNE 17, 2019

MONDAY, JUNE 17

8:30 am Registration Open and Morning Coffee

CONNECTED DIAGNOSTICS: IoT, SENSORS AND WEARABLES BRING POINT-OF-CARE Dx TO THE PATIENT

9:00 Welcome and Opening Remarks

Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

9:10 Towards Smart and Connected Point of Care Molecular Diagnostics of Infectious Diseases

Changchun Liu, PhD, Associate Professor, Biomedical Engineering Department, University of Connecticut

Smartphones have a growing and pervasive influence on our daily life. Especially with the rapid development of microfluidics technology, the incorporation of microfluidics technology with smartphone-based detection technology will create a new paradigm shift towards affordable, smart and connected health monitoring. In this talk, I will introduce our molecular diagnostic chips, smart connected devices and their applications in cervical cancer screening and infectious disease detection at the point of care.

9:40 Portability and Security for the Next Generation Point-of-Care Diagnostics

Yuksel Temiz, PhD, Research Staff Member, IBM Research-Zurich

Diagnostic technologies based on microfluidics and IoT represent a strong opportunity for providing sensitive, low-cost, rapid and connected diagnostics at the point-of-care. In this presentation, I will share our vision on a portable and connected diagnostic platform, which uses capillary-driven microfluidics and compact peripherals enabling communication with a smartphone. I will also discuss our recent efforts on the development of security features that can protect diagnostic tests from counterfeiting.

10:10 Using AI to Enable IoT and Diagnostics Devices to Deliver Personalized Care at Global Scale

Ting Shih, MBA, MS, CEO & Founder, ClickMedix

Technological advances made possible rapid emergence of point-of-care devices. However, at scale, each device needs to work within healthcare workflows, policies, and clinical guidelines to improve the health of patients. Having worked in more than 20 countries, in this talk, Ting Shih will go over an end-to-end roadmap for deploying IoT devices, integrated with clinical protocols, personalized care plans, and payment schemes to maximize the impact of IoTs and demonstrate improvement on patient health outcomes. With the use of AI, the impact of IoTs can be magnified throughout patient populations.

10:40 Networking Coffee Break

11:10 Wearables, Ingestibles, Invisibles - New Diagnostic Platforms Enabled by Silicon and AI

Chris Van Hoof, PhD, Senior Director, Connected Health Solutions, Imec

How are highly-sensitive, AI-powered, clinical-grade diagnostics and wearables being used for early disease detection, personalized treatment and prevention? Find out how our wearable health patches can serve the field of nephrology. How fast eye tracking glasses play a role in neurodegenerative disease management. How ingestible sensors monitor gastrointestinal disorders. And how wearable sensors assist the psychiatrist. These tech and AI innovations kickstarted a health tech revolution.

11:40 Wearable Sensors and Their Importance in the Complete Digital Health Solution

Brian Murphy, PhD, Director, Product Development, Connected Sensors, Philips Medical Systems

12:10 pm IoT, AI, and Digital Twins in Healthcare Operations

Shawn Evans, Director, Edge Technologies, Valorem Reply

Sponsored by REPLY VALOREM

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Session Break

CONNECTED SENSORS AND WEARABLES FOR REMOTE PATIENT MONITORING AND CLINICAL TRIALS

1:55 Piloting a Living Lab for Evaluation and Development of Novel Digital Biomarkers

Steven Richards, PharmD, Investigator, Biomarker Development, Novartis Institutes for BioMedical Research

The incorporation of digital biomarkers in clinical trials offers the possibility of replacing poor endpoints with more sensitive measures, while lowering cost and patient burden. Prior to implementing new technologies in clinical trials, it is important to conduct feasibility studies in realistic deployment environments. Living laboratories are simulated real-world environments equipped with embedded sensors, which allow us to establish ecological validity of digital biomarkers measured at-home.

2:25 Solving the 'Last Mile' Problem in the Delivery of Cancer Care: Cyber-Physical Systems and Smart Connected Health to Support Clinical Decision Making

Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Cancer patients disconnected from resource intensive cancer centers face challenges beyond simply the disease they are dealing with. This 'last mile' problem of healthcare delivery is becoming more tractable with modern broadband connectivity and sensors. This talk will discuss major barriers from the patient and clinical workflow/integration sides as well as synergistic efforts across NCI and other agencies attempting to enable these tools for clinical applications and decision support.

2:55 Networking Refreshment Break

3:15 PANEL DISCUSSION: Future of Connected Diagnostics

Moderator: Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Panelists: Speakers of the day

Discussion topics include:

- What are the emerging applications of IoT in diagnostics and remote patient monitoring?
- What is needed for patient compliance and increased adoption?
- What IT capabilities are needed for "big data" analysis? Opportunities for AI and machine learning?
- How can this technology benefit big pharma? Applications in clinical trials, patient engagement, and digital therapeutics?
- How can connected diagnostics serve as digital biomarkers in clinical trials?

4:45 Close of Symposium

Cambridge Healthtech Institute's Inaugural

Digital Health: Pharmaceutical Executive Summit

Driving Innovation in Digital Therapeutics, Clinical Trials, and Healthcare

JUNE 18-19, 2019

TUESDAY, JUNE 18

7:00 am Registration Open and Morning Coffee

DIGITAL THERAPEUTICS

8:00 Chairperson's Remarks
Joris Van Dam, PhD, Head, Digital Therapeutics, Novartis Institutes for BioMedical Research

8:10 KEYNOTE PRESENTATION: Digital Therapeutics in Pharma
Joris Van Dam, PhD, Head, Digital Therapeutics, Novartis Institutes for BioMedical Research
Digital Therapeutics represent a novel treatment modality, where high-quality, clinically validated software applications are used for the prevention, management or treatment of disease. We will review some of our key experiences from our partnership with Pear Therapeutics that was announced in March 2018: What is the unmet need that can be addressed? What are potential synergies between digital- and pharmacotherapies? How can a large pharma organization best adopt digital therapeutics?

8:40 The Rise of Digital Therapeutics as Companions to Existing and Future Therapies
Pierre Leurent, CEO, Voluntis
Digital therapeutics (DTx) represent a new class of solutions that have the potential to improve patients' treatment experience, by enhancing the efficacy and/or safety of medications. Case studies will illustrate how these solutions are currently developed and commercialized in different therapeutic areas. Future development scenarios will be explored, including the advent of drug/DTx combination therapies.

9:10 Transforming Care Models and Business Models with Digital Medicine
David J. O'Reilly, Chief Platform Officer, Proteus Digital Health
The FDA has approved the world's first NDA for a medicine including an ingestible sensor and an associated digital care management offering. The product and the expanding digital medicine field it represents also signals the emergence of a new business model for the pharmaceutical industry, one based on the integration of medications with software, analytics and services as well as one directly linked to patient-specific outcomes as the measure of pharmaceutical value.

9:40 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

10:25 Digital Health: Design for the Behavior You Would Like to See
Christian Theil Lundgaard, PhD, Director, Digital Health Partnerships & Commercial Strategy, Novo Nordisk
Digital Health will impact and improve the real-world health outcomes experienced by people with diabetes using innovative medications from Novo Nordisk to treat type 1 and type 2 diabetes. The Digital Health initiative in Novo Nordisk takes point of departure in the connected injection device, with an aim of designing solutions that allow people with diabetes to spend less time thinking about their disease and more time living their life.

10:55 Supporting Patient Journey through Medication Managment *Sponsored by* Medisafe
Omri Shor, CEO & Co-Founder, Medisafe

11:25 PANEL DISCUSSION: Future of Digital Therapeutics
Moderator: Joris Van Dam, PhD, Head, Digital Therapeutics, Novartis Institutes for BioMedical Research
Panelists: Pierre Leurent, CEO, Voluntis
Christian Theil Lundgaard, Director, Digital Health Partnerships & Commercial Strategy, Novo Nordisk
Joel Sangerman, Chief Commercial Officer, Click Therapeutics
Discussion topics include:
- What are the emerging business models for digital therapeutics?
- How are big pharma impacted by digital therapeutics?
- What are the unmet technology needs?

11:55 Transition to Lunch

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

MOBILE HEALTH AND DIGITAL TOOLS FOR PATIENT-CENTRIC CLINICAL TRIALS

1:05 Chairperson's Remarks
Mohanad Fors, MBA, Co-Founder, Global Head of Biome - The Digital Innovation Lab by Novartis

1:10 Virtual Clinical Trials, Empowering Patients and Create 20k Trial
Mohanad Fors, MBA, Co-Founder, Global Head of Biome - The Digital Innovation Lab by Novartis
This talk will share the new landscape of the digital health ecosystem and the important role of technology to disrupt how pharma works, touching one of the key critical topics in pharma which is clinical trials and empowering the patients as part of our role in supporting the ecosystem and the patients.

1:40 KEYNOTE PRESENTATION: Principles for Transforming Clinical Trials with Digital Medicine
Peter Bergethon, MD, FAAN, FANA, Vice President and Head, Digital and Quantitative Medicine, Biogen, Inc.

2:10 The Brave New World of Voice and Chatbots: How AI-Driven Virtual Assistants Improve Pharma Brand Engagement and Rx Adherence *Sponsored by* orbita
Nathan Treloar, President & Co-Founder, Orbita
Discover why leading pharma brands are seizing the power of voice- and chatbot-powered experiences. Whether delivered via smart speakers (Amazon Echo, Google Home, etc.) or via web, mobile or other devices, virtual assistants are now leveraging conversational AI to provide FAQs, Rx support, just-in-time interventions, triaged call center escalation, and other solutions to boost patient engagement, medication adherence and brand loyalty. Demand is rising for this consumer-friendly approach not only by millennials, but also by older adults who are widely adopting new tools and technology.

2:25 Refreshment Break in the Exhibit Hall with Poster Viewing

3:10 Making Trials More Attractive, Inclusive and Manageable with Innovative Use of Connected Devices: Case Studies and Lessons Learned from a Big Pharma Company
Bert Hartog, PhD, Senior Director, Clinical Innovation, Janssen Pharmaceutica N.V.
Clinical trials are notoriously difficult to execute. Finding the right people to participate and motivating them to stay in the trial are significant challenges for study sponsors and sites. Innovative use of connected devices can be a gamechanger, reducing the trial burden, integrating trials into people's daily lives and collecting more granular data. Use cases will be presented to show how to make this happen in a big pharma environment.

3:40 KEYNOTE PRESENTATION: A Platform Approach to Real-World Evidence and Real-World Population Health Transformation
Ashish Atreja, MD, MPH, Chief Innovation Officer, Icahn School of Medicine at Mount Sinai
The practice of medicine is exponentially evolving. This evolution is fueled by value-based transformation and incentives that are aligning for continuous, proactive care, within and outside the four walls of the hospitals. To address this need, the new generation of startups is leveraging disciplines like data science, informatics, digital medicine, genomics, and AI; but this is creating a problem of plenty. In spite of more than 350,000 mobile apps for healthcare, less than 4% of patients are recommended apps by providers today..

4:10 PANEL DISCUSSION: Digital Tools in Clinical Trials
Moderator: Mohanad Fors, MBA, Co-Founder, Global Head of Biome - The Digital Innovation Lab by Novartis
Panelists:
Ashish Atreja, MD, MPH, Chief Innovation Officer, Icahn School of Medicine at Mount Sinai
Peter Bergethon, MD, FAAN, FANA, Vice President and Head, Digital and Quantitative Medicine, Biogen, Inc.
Bert Hartog, PhD, Senior Director, Clinical Innovation, Janssen Pharmaceutica N.V.
Raj Pallapothu, mHealth Global Lead, Bayer
Discussion topics include:
- How can digital technologies transform clinical trials?
- What are strategies to incorporate digital tools in clinical development?
- What are technology development needs? What areas require increased investment?
- What are the barriers to adoption of digital tools in big pharma and how to overcome them?

5:20 Welcome Reception in the Exhibit Hall with Poster Viewing

6:35 Find Your Table, Meet Your Moderator

6:40 Breakout Discussion Groups (See website for details)

7:30 Close of Day

WEDNESDAY, JUNE 19

7:00 am Registration Open and Morning Coffee

MOBILE HEALTH AT BIG PHARMA

8:00 Chairperson's Remarks
Tomasz Adamusiak, MD, PhD, Director Medical Informatics Lead, Digital Medicine & Translational Imaging, Pfizer

8:05 Digital Health Opportunities 2025
Raj Pallapothu, mHealth Global Lead, Bayer

8:35 Breakthrough Digital – Making a Positive Impact on Millions of Patients
Adrian Chernoff, MBA, Former Worldwide Vice President, Global Head of Research and Development, Johnson and Johnson
It's not every day a breakthrough product is created. From idea to market, we will cover the R&D journey in delivering digital transformation at scale at Johnson & Johnson. The result is the #1 diabetes app in the U.S. and Canada with over one million downloads. We will cover the multi-faceted dynamics of developing a breakthrough digital at scale inclusive of customer experience, putting the patient at the center, big data, agile vs. waterfall, IoT, cloud, data privacy, intelligent medical devices and remote patient monitoring.

9:05 Digital Therapeutics - A New "Pill"ar in Big Pharma
Joel Sangerman, Chief Commercial Officer, Click Therapeutics
The largest pharmaceutical companies in the world are tapping digital therapeutics companies as investors and as commercial partners in bids to treat patients with software apps as stand-alone therapies and as companions to their drugs. Hear how traditional pharma commercialization models compare with those for digital therapeutics and how payers plan to cover, reimburse, and use digital therapeutics in medical policies and prior authorization criteria for drug coverage.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

BIG DATA: AI AND MACHINE LEARNING IN DIGITAL HEALTH

10:20 Building a Digital Health Data Pipeline in the Cloud
Tomasz Adamusiak, MD, PhD, Director Medical Informatics Lead, Digital Medicine & Translational Imaging, Pfizer
The mission of the Digital Medicine group and the Pfizer Innovation Research (PfIRe) Lab is to solve key business problems using dynamical measures and advanced STEM platforms. Our goal is to utilize digital remote monitoring of patients' symptoms to develop and validate novel clinical endpoints for disease diagnosis and health state assessment. This presentation will explore the unique challenges of digital biomarkers from a data engineering and knowledge management perspective.

10:50 Humanizing Care through AI
Kamal Jethwani, MD, MPH, Senior Director, Pivot Labs, Partners HealthCare; Assistant Professor, Harvard Medical School
Health systems and healthcare industries are eagerly diving into AI and machine learning technologies, allocating significant resources toward validating and refining predictive algorithms for a range of applications, including diagnostic tools and aids to clinical decision making. However, we need to understand the human users of these algorithms, and how their clinical workflows, decisions, and relationships with patients will be affected, and how best to position AI for success in the delivery of care.

11:20 Precision Healthcare through Multi-Scale Biomedical Data Integration
Jessilyn Pearl Dunn, PhD, Assistant Professor, Biomedical Engineering and Biostatistics & Bioinformatics, Duke University
Recent technological advancements make it possible to closely and continuously monitor individuals on multiple scales in real time while also incorporating genetic, environmental, and lifestyle information. We are collecting and using this multi-scale biomedical data to gain a more precise understanding of health and disease at molecular and physiological levels and developing actionable, predictive health models for improving cardiometabolic outcomes.

11:50 Transition to Lunch

12:00 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Transition to Plenary

12:55 PLENARY KEYNOTE: Controlling Prescription Drug Pricing: Where is it Headed?
Ed Silverman, Pharmalot Columnist, Senior Writer, STAT

1:30 PLENARY PANEL DISCUSSION: Data Driven Drug Discovery and Development: Digital, AI and ML to Re-Shape R&D
Moderator: Peter Henstock, PhD, AI & Machine Learning Lead, Pfizer
Panelists:
Litao Zhang, PhD, Vice President, Leads Discovery and Optimization, Bristol-Myers
Jamileh Jemison, MS, MD, Head of Clinical Development, Healthmode
Christine Dingivan, PhD, Global Drug Development Head, Data and Digital, Novartis
Peter Bergethon, Vice President, Quantitative Medicine & Clinical Technologies, Biogen

2:20 Dessert and Coffee Break in the Exhibit Hall with Poster Viewing

3:05 Close of Conference

Cambridge Healthtech Institute's 2nd Annual

Digital Biomarkers: Biosensors, Wearables, and mHealth

Clinical Utility and Emerging Applications in Drug Development

JUNE 19-20, 2019

WEDNESDAY, JUNE 19

12:00 pm Registration Open

12:00 Bridging Luncheon Presentation: Advancing High-Throughput Screening Using FirePlex-HT Immunoassays

Sponsored by abcam

Elnaz Atabakhsh, PhD, Senior Product Manager, Multiplex Assays, Abcam

To address the need for high-throughput and sensitive quantification of protein biomarkers from biological samples, we at Abcam have developed FirePlex®-HT immunoassays: a high-throughput multiplex platform that can quantify 10 protein analytes per well in a 384-well format. FirePlex-HT is ideally suited to drug discovery projects screening large compound libraries, safety assessment and toxicity screening in large sample sets, and clinical focused studies for disease identification, patient stratification or therapy responses in large patient cohorts.

12:30 Transition to Plenary

12:50 PLENARY PANEL DISCUSSION: Data Driven Drug Discovery and Development: Digital, AI and ML to Re-Shape R&D

Moderator: Peter Henstock, PhD, AI & Machine Learning Lead, Pfizer

Panelists:

Litao Zhang, PhD, Vice President, Leads Discovery and Optimization, Bristol-Myers

Jamileh Jemison, MS, MD, Head of Clinical Development, Healthmode

Christine Dingivan, PhD, Global Drug Development Head, Data and Digital, Novartis

Peter Bergethon, Vice President, Quantitative Medicine & Clinical Technologies, Biogen

WPW WORLD PHARMA WEEK

2:20 Dessert and Coffee Break in the Exhibit Hall with Poster Viewing

REAL-WORLD EVIDENCE: UTILITY OF DIGITAL BIOMARKERS

3:05 Chairperson's Remarks

Wasim Malik, PhD, Professor, Harvard Medical School; Managing Director, Iaso Ventures

3:10 The Use of RWE and AI to Improve Patient Outcomes

Bernard Hamelin, MD, Head, Medical Evidence Generation, Sanofi

Data is the currency of drug research and development and medical knowledge. The huge technical advances that have been evolving about evidence generation, analyzing and sharing data are allowing drug companies to better respond to physicians, regulators, payers and patients' requirements. At the same time, there are risks that come along with these advances which makes it important to develop a structured approach to help companies deal with various cultural, administrative and legal complexities.

3:40 Digital Biomarkers and Real-World Evidence in Clinical Research

Wasim Malik, PhD, Professor, Harvard Medical School; Managing Director, Iaso Ventures

The myriad complexities and challenges of the drug development process motivate the rethinking of the entire value chain with the goal of identifying opportunities for radical changes in clinical trial design.This talk will discuss the potential of real-world evidence and digital biomarkers in enabling rapid drug development for the benefit of patients, identifying lessons that can be learned from other data-driven industries and discussing successful examples of technology-enabled approaches to clinical trials.

4:10 Data and Metadata Standards for Real-World Digital Biomarkers

Ida Sim, MD, PhD, Co-Founder, Open mHealth; Professor, Medicine, University of California, San Francisco

The digital health ecosystem would function more effectively if there was judicious standardization of digital biomarkers to facilitate data sharing. Moreover, data and metadata standards are needed to enable efficient real-world monitoring of multitudes of devices at scale for regulatory purposes. This talk will review the current state of digital biomarker standardization and the relationship to electronic health record data standards.

4:40 Digital Biomarkers: A Path to Meaningful Real-World Evidence

Jamileh Jemison, MS, MD, Head of Clinical Development, HealthMode

Successful clinical development and post-approval adoption hinge on clean, relevant data. With continuous, tailored data-measurement tools emerging, the future looks bright for focused passive data collection using latent technologies. Using examples from our work, I will discuss the future applications of continuous, customizable measurement in clinical research.

5:10 Networking Reception in the Exhibit Hall with Poster Viewing

6:05 Close of Day

THURSDAY, JUNE 20

7:15 am Registration Open

7:15 Breakout Discussion Groups with Continental Breakfast (See website for details)

DIGITAL BIOMARKERS AS CLINICAL ENDPOINTS

8:10 Chairperson's Remarks

Michael J. Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline

8:15 Challenges and Opportunities in Implementing Digital Biomarkers in Clinical Trials

Balaji Goparaju, Data Scientist, Innovative Digital Endpoints Analytics, Novartis

Digital biomarkers sit in an exciting intersection of the development of biology, novel analytics, and sensor technology. Digital biomarkers have the potential to complete the causal chain using continuous measurements to inform out-of-office behavior. However, much of the hype around transforming clinical trials using sensor technology will have to face the scientific, operational, and financial challenges that need to be addressed before wearables can consistently generate impact for the pharmaceutical industry.

8:45 A Platform Approach to Evaluating Digital Drug Development Technologies

Joshua Cosman, PhD, Quantitative Medicine, Digital Innovation, Biogen

Digital drug development technologies present an opportunity for more frequent, objective functional outcomes across a range of neurological disorders. In this talk, I provide an overview of our ongoing work in the PD and ALS space evaluating wearable and mobile assessments, including operational aspects, precompetitive alignment across industry and academic partners, and our interactions with regulators.

9:15 Transforming Clinical Trials with Objective, Holistic, Continuous and Ecologically Valid Digital Assessment

Jeffrey Kaye, MD, Layton Professor, Neurology & Biomedical Engineering, Director, ORCATECH - Oregon Center for Aging & Technology, Oregon Health & Science University

Trials have been limited by brief, episodic examinations relying on surrogate markers and much subjective data as outcomes. This presentation will describe an integrated, home-based pervasive computing platform deployed to hundreds of homes, and designed to improve trials by capturing objective, holistic, 24/7, and ecologically valid data. The data's density, reflection of real-world function and person-specificity can reduce sample sizes or time needed to obtain early meaningful signals of clinical efficacy and safety.

9:45 Using Deep Learning to Generate Novel Digital Biomarkers: A Wearables-Based Proxy for VO2max

Sponsored by physIQ

Chris Economos, Vice President, Business Development, physIQ

Matt Pipke, CTO, physIQ

There are many "gold standard" clinical assessments that, while accepted by industry and regulators, are far from ideal. They are either too expensive (polysomnography), too inaccurate (6 minute walk), or too burdensome (VO2max). Physiology data from wearable sensors, when coupled with deep-learning artificial intelligence, provide the opportunity to replicate these assessments at home. In this presentation physIQ will review their latest proprietary deep learning tool as a potential replacement for VO2max in clinical trials.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

mHEALTH PLATFORMS FOR DIGITAL BIOMARKERS: MOBILE DEVICES AND APPS

11:00 Regulatory Considerations During Mobile Medical App Development

Michael J. Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline

This presentation will cover: 1) Mobile Medical Apps (MMAs) are defined as medical devices from its intended use shown through labeling claims, advertising, oral or written statements; 2) MMA regulation is health risk based to balance patient safety and regulatory barriers to technological innovation, 3) Patient risk analysis is a critical activity prior to sensor/app inclusion within a clinical trial; 4) Digital Safety Risks include Data Privacy, Data Cybersecurity, Software Malfunction and Clinical Risk from app/sensor use.

11:30 The Asthma Mobile Health Study Latest Research Findings

Yu-Feng (Yvonne) Chan, MD, PhD, Associate Professor, Genetics & Genomics Sciences, Icahn School of Medicine; Director, Digital Health & Personalized Medicine, Icahn Institute for Genomics and Multiscale Biology at Mt. Sinai

The Mount Sinai Asthma Mobile Health Study powered by Apple's ResearchKit framework is a remote observation study that enrolled >10,000 participants from 3 countries. Yvonne Chan, MD, PhD, principal investigator of the study and Director of the Center for Digital Health at Icahn School of Medicine at Mount Sinai, will share the latest lessons learned from this pioneering mobile health research study.

12:00 pm Precision Medicine on the Cloud

Iman Tavassoly, MD, PhD, Physician-Scientist, Icahn School of Medicine at Mount Sinai

Computational and mathematical models of human physiological and pathological processes can be used as a platform to monitor and control disease conditions by cloud computing. Input data are provided by biosensors and wearables, and the data processing using mathematical models is done on the cloud. In this talk I will give an overview and details of cloud computing strategy for precision medicine.

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Transition to Lunch

1:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Dessert and Coffee Break in the Exhibit Hall with Poster Viewing

BIOSENSORS AND WEARABLES AS NOVEL DIGITAL BIOMARKERS

2:20 Chairperson's Remarks

Carrie Northcott, PhD, Research Project Lead, Digital Medicine and Translational Imaging (DMTI), Early Clinical Development, Pfizer, Inc.

2:25 Talk Title to be Announced

Andy Coravos, Co-founder & CEO, Elektra Labs

2:55 The Verification and Use of Digital Wearable Technology to Evaluate Scratching and Sleep in Atopic Dermatitis

Carrie Northcott, PhD, Research Project Lead, Digital Medicine and Translational Imaging (DMTI), Early Clinical Development, Pfizer, Inc.

Atopic dermatitis is often accompanied by unrelenting nighttime pruritus resulting in reduced sleep. Quantitatively evaluating nighttime scratch and sleep via accelerometry using digital wearables to continuously monitor patients in their "home environment" would provide insight into the disease and effectiveness of treatments. A key aspect to provide value in these assessments is that the methods and devices are vetted and verified to detect clinically meaningful changes.

3:25 Shaping the Future of Digital Health Technologies in Parkinson's Research

Julia Keefe, Associate Director, Research Programs, Michael J. Fox Foundation

The Michael J. Fox Foundation for Parkinson's Research collaborates with leading researchers, industry partners, and the data science community to generate and analyze robust sensor-based datasets. In this talk, Lauren will report on results and best practices that are bringing us closer than ever to developing clinically meaningful endpoints and using them to support Parkinson's disease clinical development.

3:55 Close of Conference

Hotel & Travel Information

Conference Venue:
Seaport World Trade Center
200 Seaport Boulevard
Boston, MA 02210

Host Hotel:
Seaport Hotel
One Seaport Lane
Boston, MA 02210

Reservations: Go to PharmaWeek.com/Travel

Discounted Room Rate: $325 s/d

Discounted Room Rate Cut-off Date: May 13, 2019

Pricing and Registration Information

CONFERENCE PRICING

	Commercial	Academic, Government, Hospital-affiliated
BEST VALUE		
(Includes access to all Conferences/Training Seminars at World Pharma Week (Including Biomarker World Congress, World Preclinical Conference, IO Pharma Congress, and Digital Health Pharma Congress.) (Does not include access to Symposia or Short Courses.))		
Registrations After May 10, 2019 and On-Site	$2,499	$999
CONGRESS PRICING		
(Includes access to ONE Conference/Training Seminar for 1.5 days. Does not include access to Symposia or Short Courses.)		
Registrations After May 10, 2019 and On-Site	$2,099	$499

JUNE 17, 2019	JUNE 18-19, 2019	JUNE 19-20, 2019
Symposium: Internet of Diagnostic Things	Digital Health: Pharmaceutical Executive Summit	Digital Biomarkers: Biosensors, Wearables, and mHealth

SHORT COURSE PRICING		
1 Short Course	$749	$429
2 Short Courses	$1,049	$729
3 Short Courses	$1,249	$829
4 Short Courses	$1,449	$929
SYMPOSIA PRICING		
1 Symposium	$999	$699

CONFERENCE DISCOUNTS

Poster Submission - **Discount ($50 Off)**: Poster abstracts are due by May 3, 2019. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Alumni Discount: Cambridge Healthtech Institute (CHI) appreciates your past participation at World Preclinical Congress and/or Biomarker World Congress. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Jeff Knight at jknight@healthtech.com, 781-247-6264.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/Cancellations Policy, go to healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

If you are unable to attend but would like to purchase the World Pharma Week CD for $750 (plus shipping), please visit PharmaWeek.com. Massachusetts delivery will include sales tax.

How to Register: PharmaWeek.com

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **DH F** when registering!

Please refer to the Registration Code below:

Cambridge HEALTHTECH Institute

A Division of Cambridge Innovation Institute

250 First Avenue, Suite 300
Needham, MA 02494
Healthtech.com
Fax: 781-972-5425