IPAC-RS Digital Devices Roundtable Series:

WHAT IS A DIGITAL BIOMARKER AND WHY IS IT IMPORTANT?

September 10, 2021
Bios

Moderators:

Marta Lombardini, Ph.D.
Device Development Manager
Chiesi Group
m.lombardini@chiesi.com

Dr. Marta Lombardini is an Experienced Device Development Manager with a demonstrated history of working in the pharmaceuticals industry. Skilled in Device development processes, Agile Design, Human factors sciences, Product and process Validation, Documentation generation, Regulations and Product submissions. Enthusiastic professional with a Doctor of Philosophy (PhD) focused in Electronics and Biomedical/Medical Engineering from University of Bologna. Marta's aim is to develop products to improve quality of life. Since she firstly joined Chiesi in 2016 she has strongly contributed at spreading the Customer Centric design approach. She has experience in developing diverse type of device constituent part in combination products naming Syringes, Nebulizers and other electromechanics delivery systems. She is particularly interested in studying and collecting behavioral data that can be used to explain, influence, and predict health-related outcomes and she enjoys managing the diversity of the different projects which can include digital devices. Marta has always had a strong focus at standardizing the approach to get to the best outcome and performance of the systems we design. Prior to joining Chiesi she has been part of the Philips healthcare Respironics group and learned how to enhance medical products development using the human factors and risk based approach as a competitive advantage for achieving what is really needed in the market creating loyalty and ensuring it can be safely, efficaciously and pleasantly used by the final customers.

Lee M. Nagao, Ph.D.
Senior Director, Science, Regulation & Policy
Faegre Drinker Biddle & Reath LLP, IPAC-RS Secretariat
lee.nagao@faegredrinker.com

Lee M. Nagao, Ph.D., is a Senior Director of Science, Regulation and Policy at the law firm of Faegre, Drinker, Biddle and Reath, LLP, and is a member of the Firm's Life Sciences Consortium Management and Regulatory Affairs Practice Group. The Group works extensively with pharmaceutical, biopharmaceutical and medical device companies on a range of scientific and regulatory collaborations and provides strategic and regulatory guidance to individual life sciences companies. Lee plays a lead role serving scientific and regulatory consortia including the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), the Extractables and Leachables Safety Information Exchange (ELSIE), and the International Pharmaceutical Consortium on Innovation and Quality (IQ). Lee has extensively published and presented on many aspects of pharmaceutical development including supply chain, CMC, and translational sciences. She has represented various industry groups before regulatory and scientific agencies and organizations in the US, Europe and Asia, including the FDA, EMA, China NIFDC, Chinese Pharmacopoeia, ANVISA, Taiwan CDE, Japan PMDA, and USP.

Speakers:

Marissa Dockendorf, Ph.D.
Director, Global Digital Analytics & Technologies
Merck Research Laboratories
marissa.dockendorf@merck.com

Dr. Marissa Dockendorf is a Director in the Global Digital Analytics & Technologies group and has 15 years of experience in pharmaceutical R&D. Marissa provides strategic oversight for adoption of digital health approaches across Merck's portfolio and leads a team of scientists in evaluating emerging digital technologies, enabling their adoption in clinical trials, and in developing digital endpoints. She plays a critical role in Merck's digitally-enabled clinical trials initiative, which is focused on introduction of digital technologies and outpatient sampling approaches into clinical trials to reduce patient burden, collect higher quality data, enrich clinical trial data sets, and enable more rapid and informed drug development decisions. Since originally joining Merck in 2006, she's provided pharmacokinetic and pharmacometric expertise and scientific oversight for many programs across the discovery-development continuum and spanning multiple therapeutic areas. She's held roles of increasing responsibility, including disease and therapeutic area level scientific leadership positions in quantitative pharmacology & pharmacometrics for the areas of cardiovascular disease, neuroscience, and ophthalmology. Prior to rejoining Merck in 2011, she worked on ocular drug delivery research projects at Vistakon, a Division of Johnson & Johnson Vision Care. Marissa has a PhD in chemical engineering and a master's degree in biomedical engineering from the University of Florida and an undergraduate degree from the Illinois Institute of Technology.

Bryan J. Hansen, Ph.D.
Associate Principal Scientist, Global Digital Analytics and Technologies
Merck Research Laboratories
bryan.hansen@merck.com

Dr. Bryan J. Hansen is an Associate Principal Scientist in the Global Digital Analytics and Technologies team at Merck Research Laboratories, where his responsibilities include identifying clinically meaningful digital biomarkers from biosensors, smartphones, and different types of active and passive data streams. Currently, he is leading a diverse team of clinicians and researchers to identify novel digital biomarkers in a variety of neurodegenerative and neuropsychiatric diseases. Dr. Hansen is both a trained neuroscientist and exceptional at data analysis, effectively bridging the gap between biology and computation. His research has also been uniquely diverse, beginning in animal models, extending his findings to patients with epilepsy, and finally to digitally-enabled clinical trials. This work has been published and cited in many high-profile journals and presented internationally. Before joining Merck in 2015, Bryan was a post-doctoral fellow at the Salk Institute for Biological Studies in the Systems Neurobiology Laboratories, where his work focused on neural mechanisms underlying attention-related changes in brain state. Bryan received his doctorate in Biomedical Sciences from the University of Texas Health Science Center with a focus on systems/computational neuroscience and a Bachelor's in Neuroscience from Baylor University.

James Blakemore, Ph.D.
Senior Consultant, Strategy Group, Medical Technology Division
Cambridge Consultants
james.blakemore@cambridgeconsultants.com

James is a Senior Consultant within Cambridge Consultants' Strategy & Definition group. He oversees portfolio development, market analysis and transaction support assignments on behalf of biopharmaceutical, medical device and investment companies. Project experience includes the application of digital strategies to add stakeholder value to pharmaceutical, drug delivery and diagnostic solutions. James has over 20 years' experience in medical markets, and previously worked in licensing roles for pharmaceutical and biotechnology companies towards the identification, validation and commercialisation of broad new therapies. He has a PhD in Molecular Neuroscience from King's College, University of London, and a BSc in Molecular Biology from Edinburgh University.

Joe Corrigan, CEng MIMechE
Head of Intelligent Healthcare
Global Medical Technology, Cambridge Consultants
joe.corrigan@cambridgeconsultants.com

Joe is Head of Intelligent Healthcare at Cambridge Consultants and has responsibility for developing digital services and connected medical devices that incorporate elements of advanced biosensing & biomarkers, machine learning & AI.

Currently Joe is working on a number of connected platforms including biomarker discovery and optimization for both connected pharmaceutical strategies and breakthrough innovations in minimally invasive surgical and nonsurgical procedures. Prior to joining Cambridge Consultants, Joe founded two startups in medical technology and machine learning and demonstrated methods for measuring spatially correlated vulnerable plaque biomarkers of cardiovascular disease in-vivo. Joe is a Chartered Engineer and holds a master's degree in mechanical engineering from UMIST with a specialism in thermofluids.