Duke | Robert J. Margolis, MD Center for Health Policy

Developing Study Endpoints in Real-World Settings

Duke-Robert J. Margolis, MD, Center for Health Policy
Virtual Meeting
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Biographies

Jennifer Goldsack is the co-founder and serves as the Executive Director of the Digital Medicine Society (DiMe), a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. Jen's research focuses on applied approaches to the safe, effective, and equitable use of digital technologies to improve health, healthcare, and health research. She is a member of the Roundtable on Genomics and Precision Health at the National Academies of Science, Engineering and Medicine. Previously, Jen spent several years at the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA. There, she led development and implementation of several projects within CTTI's Digital Program and was the operational co-lead on the first randomized clinical trial using FDA's Sentinel System. Jen spent five years working in research at the Hospital of the University of Pennsylvania, first in Outcomes Research in the Department of Surgery and later in the Department of Medicine. More recently, she helped launch the Value Institute, a pragmatic research and innovation center embedded in a large academic medical center in Delaware. Jen earned her master's degree in chemistry from the University of Oxford, England, her masters in the history and sociology of medicine from the University of Pennsylvania, and her MBA from the George Washington University. Additionally, she is a certified Lean Six Sigma Green Belt and a Certified Professional in Healthcare Quality. Ms. Goldsack is a retired athlete, formerly a Pan American Games Champion, Olympian, and World Championship silver medalist.

Bellinda King-Kallimanis is Director of Patient-Focused Research at LUNGevity. Dr. King-Kallimanis has worked in patient-focused research for the past 17 years. Before joining LUNGevity, she worked at the US Food and Drug Administration Oncology Center of Excellence on the Patient-Focused Drug Development team. There, Bellinda worked on the development and launch of Project Patient Voice, a resource for patients and caregivers along with their healthcare providers to look at patient-reported symptom data collected from cancer clinical trials. Bellinda also has experience in industry and academia and has published over 60 peer-reviewed papers that cover disease areas like lung cancer, depression, cognitive impairment and multiple sclerosis. She received her bachelor of applied science and her master of science in applied statistics from Swinburne University of Technology in Melbourne, Australia, and her Ph.D. in psychometrics from the Academic Medical Center in Amsterdam, Netherlands.

Eric G. Klein is Senior Director, Oncology in the Global Patient Outcomes and Real-World Evidence Department at Eli Lilly and Company. In this role Eric leads the Outcomes Research team supporting the Oncology Business Unit and is responsible for the health economic, outcomes research, and real-world evidence capabilities supporting Lilly's early and late phase drug development oncology portfolio as well as the marketed oncology portfolio in the US. Dr. Klein has spent the last 20 years in leadership roles responsible for various aspects of the Outcomes Research and Real-World Evidence organization at Lilly. Eric joined the Outcomes Research organization of Lilly USA in January of 1998 where he spent 6 years focused on building the organizations Outcomes Liaison capabilities. In September 2004 Eric transitioned to Lilly's Global Health Outcomes organization where Eric held leadership roles associated with development across product and program phase research as well as the development of business management and operations capabilities including quality, capacity planning, capability management and development, strategic planning, and project management. In January of 2010, Eric returned to Lilly USA to assume responsibilities for strategic transformation efforts within the Outcomes Research organization and then in 2011, Eric took on responsibility for the Regional Outcomes Research teams globally. Eric assumed his current responsibilities in Oncology drug development in 2014.

Kerra Mercon is a senior research assistant at the Duke-Margolis Center for Health Policy working on projects related to biomedical innovation and real-world evidence. Her work focuses on advancing the use of real-world data and evidence to support regulatory decision-making regarding the effectiveness of medical products. Kerra received her Master's degree from George Washington University in Biomedical Engineering and her Bachelor's Degree from Bucknell University in Mechanical Engineering, where she conducted research on designing affordable and accessible medical devices.

Linda Nelsen is Senior Director and Head, Oncology Patient Centered Outcomes at GlaxoSmithKline. The Oncology PCO team at GSK is responsible for the development and implementation of innovative patient centered outcome strategies within oncology. Prior to joining GSK, Ms. Nelsen was a Director of Epidemiology at Merck Sharp & Dohme where she led development of PRO strategies in respiratory and other disease areas. She is active in external initiatives, including serving as Industry Co-Director of the Critical Path Institutes' PRO Consortium. Linda has a master's degree in Epidemiology from the Johns Hopkins University Bloomberg School of Public Health, and conducted epidemiology research at medical research institutions prior to joining the pharmaceutical industry. With over 20 years of experience in patient centered outcomes research, Linda is focused on ensuring implementation of well-defined patient centered outcomes strategies that capture the patient voice in clinical trials and articulate patient experience of treatment benefit and risk.

Elisabeth M. Oehrlein is Senior Director, Research & Programs at the National Health Council, joining the organization in July 2018. In this role, Dr. Oehrlein crafts the NHC's annual research and programmatic agenda in service to their mission and leads the NHC's research and programmatic work on value, real-world evidence, and patient engagement. She is a mixed-methods researcher with expertise in epidemiologic, qualitative, and patient-engagement methods, as well as patient-focused medical product development. Her research interests include developing new methods for applying patient-provided information when developing real-world evidence to ensure studies reflect the "real world" as closely as possible, as well as developing new methods for patient-journey mapping. Dr. Oehrlein holds a BA degree from Franklin & Marshall College, an MS in Epidemiology from the University of Maryland School of Medicine's Department of Epidemiology and Human Genetics, and a Ph.D. in Pharmaceutical Health Services Research with a concentration in Comparative Effectiveness Research/Patient-Centered Outcomes Research from the University of Maryland School of Pharmacy. She is an active member of the International Society for Pharmacoeconomics and Outcomes Research and holds leadership roles in the Patient-Centered and Real-World Evidence Special Interest Groups.

Bryce Reeve is a Professor of Population Health Sciences and Professor of Pediatrics at Duke University School of Medicine. He also serves as Director of the Center for Health Measurement since 2017. Trained in psychometric methods, Dr. Reeve's work focuses on assessing the impact of disease and treatments on the lives of patients and their caregivers. This includes the development of clinical outcome assessments using both qualitative and quantitative methods, and the integration of patient-centered data in research and healthcare delivery settings to inform decision-making. From 2000 to 2010, Dr. Reeve served as Program Director for the U.S. National Cancer Institute. From 2010 to 2017, he served as Professor of Health Policy and Management at the University of North Carolina. From 2011-2013, Dr. Reeve served as President of the International Society for Quality of Life Research (ISOQOL). In 2015, he received the John Ware and Alvin Tarlov Career Achievement Prize in Patient-Reported Outcomes Measures. In 2017, 2018, and 2019, he was ranked in the top 1% most-cited in his respective field over the past 11-year period.

Vincent J. Willey is a Principal Scientist at HealthCore with research interests including diabetes, cardiovascular disease, respiratory disease, mental health and oncology. He has published over 50 manuscripts in peer reviewed journals and presented research at hundreds of medical, pharmacy and research meetings. Dr. Willey maintains his status as a Board Certified Ambulatory Care pharmacist and is formerly an Associate Professor of Pharmacy and Vice Chair at the Philadelphia College of Pharmacy within the University of the Sciences. At HealthCore, he is responsible for developing HealthCore's unique and differentiating subject-matter-expertise in the design and conduct of Pragmatic Clinical Trials as well as supporting the design, implementation and interpretation of progressive study designs.

Duke-Margolis Moderator

Mark McClellan is Director of the Margolis Center for Health Policy at Duke University and the Robert J. Margolis Professor of Business, Medicine, and Policy. He is a physician economist who focuses on quality and value in health care including payment reform, real-world evidence and more effective drug and device innovation. He is former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. He was previously Senior Fellow at the Brookings Institution and a faculty member at Stanford University.