



Symposium 6: Japan In Real Life: Data, evidence and an evolving regulatory framework for Pharmacovigilance

Moderator

Robert Reynolds FISPE, GSK R&D, USA



Dr. Reynolds is Vice President, Epidemiology in GSK's Value, Evidence and Outcomes organization, part of Research and Development. He is also an Adjunct Associate Professor of Epidemiology at Tulane School of Public Health and Tropical Medicine. He is a Fellow and former Board member of the International Society for Pharmacoepidemiology. Prior to joining the GSK, he was Vice President, Epidemiology at Pfizer in the Worldwide Regulatory and Safety organization for twenty years. He holds a BA in Biology from Bard College and a MSc in Epidemiology and ScD in Population and International Health from the Harvard School of Public Health.

Speakers

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Masato Takeuchi, Kyoto University, Japan



Masato Takeuchi received MD degree from Nagoya City University, MPH and PhD degree from The University of Tokyo. He is currently working as an associate professor at Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyoto University. His research interests are Pharmacoepidemiology/Clinical Epidemiology and Machine Learning.

Takashi Ando, Pharmaceuticals and Medical Devices Agency, Japan



Mr. Takashi Ando is an epidemiologist in Division of Epidemiology, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. He joined PMDA in 2014 and he was assigned to the team for epidemiological analysis and review for drug safety assessments, through the Medical Information for Risk Assessment Initiative (MIHARI Project). Since 2014, also as a member of MID-NET® project to provide electronic medical record database for drug safety assessments in Japan, he has contributed to verification of MID-NET® system reliability and utilized MID-NET® for post-marketing drug safety assessments.

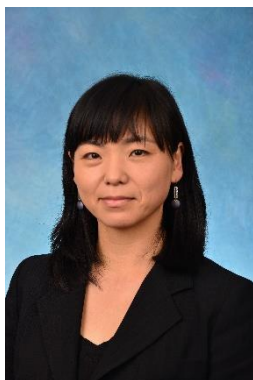
Cynthia de Luise, Pfizer, USA



Cynthia de Luise, MPH, PhD, PA, is a senior pharmacopidemiologist in the Worldwide Medical and Safety organization at Pfizer with over 25 years of experience in pharmaceutical drug safety research and clinical medicine. Prior to joining Pfizer in 2001 she had a successful career as a physician assistant in surgical critical care. At Pfizer she supports products across multiple therapeutic areas and drug safety issues and has significant expertise using real world data for safety, effectiveness, drug utilization and validation studies. Over the last several years she has led a long-term initiative to develop pharmacoepidemiologic capabilities in Japan, which has included hospital-based validation studies of claims data and scientific oversight of the first post-marketing safety study using the Japan MID-NET. Her product support includes

Pfizer's first in class CDK 4/6 inhibitor, Ibrance for which she developed novel predictive models to identify early and advanced ER+/HER2- breast cancer in administrative claims data, the meningitis B vaccine, Trumenba, and Pfizer's biosimilar oncology portfolio. Cynthia is an Adjunct Associate Professor of Epidemiology at Rutgers School of Public Health and received her PhD in Public Health/Epidemiology from Rutgers School of Public Health and a MPH in Epidemiology from Columbia Mailman School of Public Health.

Soko Setoguchi FISPE, Rutgers University, USA



Soko Setoguchi, MD, DrPH, FISPE, a cardiologist by training, US board-certified internist, and pharmacoepidemiologist, is Associate Professor of Medicine and Epidemiology, Director of Clinical Research Education, Department of Medicine, Rutgers Robert Wood Johnson Medical School and Co-Director of the Master of Science in Clinical and Translational Science at Rutgers School of Graduate Studies. After her medical school and Cardiology training in Japan, she completed her doctoral training in epidemiology at the Harvard School of Public Health. Dr. Setoguchi is recognized as an international leader in the field of pharmacoepidemiology. She has authored more than 120 peer-reviewed papers, and has successfully obtained federal and non-federal grants for her pharmacoepidemiology research program. Her research uses real

world data to perform health services/outcomes research and comparative effectiveness research for medications and implantable medical devices in patients with chronic disease. She has produced critical insights to improve the health outcomes of patients with chronic disease. Her work is internationally regarded for its methodological rigor and creativity. As she tackled important research questions, she used, promoted, and developed/tested various methods to conduct valid studies including 1) data linkage, 2) design-based and analytic methods for pharmacoepidemiologic studies, and 3) validation studies.