# Symposium 1: Variability and generalizability of claims-based algorithms in pharmacoepidemiologic research: Multinational perspectives

## Moderators

### 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.

### Chieko Ishiguro, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Dr. Chieko Ishiguro is a senior epidemiologist in the Office of Medical Epidemiology at the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. She has over 10 years' experience at PMDA. During 2009-2013, she established the team for epidemiological analysis and review for drug safety assessment, through the Medical Information for Risk Assessment Initiative (MIHARI Project). Since 2010, she has been responsible for leading epidemiological studies using healthcare information databases, including the National Claim Database and the electronic medical record database named MID-NET®, and also for reviewing post-marketing study protocols submitted by pharmaceutical industries to PMDA.

She also has experience as a visiting scientist in the Office of Safety and Epidemiology in the Food and Drug Administration and the School of Public Health, at Boston University in Massachusetts in 2010. She is the recipient of the Best Reviewer Award of Pharmacoepidemiology and Drug Safety for 2016. She has been a board member of the

International Society for Pharmacoepidemiology (ISPE) since 2018, and also a councilor of the Japanese Society for Pharmacoepidemiology (JSPE) since 2015.

## Speakers

### Brian Strom FISPE, Rutgers University, USA

Brian L. Strom, M.D., M.P.H. is the Inaugural Chancellor of Rutgers Biomedical and Health Sciences (RBHS) and the Executive Vice President for Health Affairs at Rutgers University. RBHS is comprised of eight schools and seven major centers/institutes, and includes academic, patient care, and research facilities. Dr. Strom was formerly the Executive Vice Dean of Institutional Affairs, Founding Chair of the Department of Biostatistics and Epidemiology, Founding Director of the Center for Clinical Epidemiology and Biostatistics, and Founding Director of the Graduate Program in Epidemiology and Biostatistics, all at the Perelman School of Medicine of the University of Pennsylvania (Penn).

Although Dr. Strom's interests span many areas of clinical epidemiology, his major research interest is in the field of pharmacoepidemiology, i.e., the application of epidemiologic methods to the study of drug use and effects. He is recognized as a founder of this field and for his pioneer work in using large automated databases for research.

### 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.

### Benjamin Daniels, University of New South Wales, Australia

Dr. Benjamin Daniels is an early-career pharmacoepidemiologist, specialising in the analysis of linked administrative health data to understand the use and outcomes of medicines, with a particular focus on targeted cancer therapies. Ben has over 8 years of experience as a biostatistician and data analyst, leading analyses for multi-disciplinary research teams spanning laboratory-based, epidemiology, and public health research at UNSW and the University of Sydney; and translating findings to clinical and policy audiences. He is currently a Postdoctoral Research Fellow within the Medicines Policy Research Unit at the CBDRH.