Symposium 2: Data science and Pharmacoepidemiology in the next 10 Years

Moderator

Wei Zhou FISPE, Wei Zhou, Merck Research Laboratories, USA

Wei Zhou, MD, Ph.D., is currently Executive Director and head for Oncology, Pharmacoepidemiology, Center for Observational and Real-world Evidence (CORE) at Merck Research Laboratories. Before that, he was the Executive Director at CORE Product Line, Regional Director and Head of Epidemiology Asia Pacific Unit at Merck, Director of Molecular Epidemiology at Pfizer Oncology, and Senior Epidemiologist at Merck. Wei was a Research Fellow/Research Associate/ Research Scientist at Harvard School of Public Health between June 1999 and December, 2007, where he had contributed to a number of projects on gene-environment interactions in the development and prognosis of different chronic diseases including cancers. Wei is a Fellow of the International Society of Pharmacoepidemiology (ISPE).

Wei received his MD from West China University of Medical Sciences in 1994 and Ph.D of Environmental Health from Shanghai Medical University in 1998. He was the recipient of the John E. Fogarty International Training and Research Program. He has published more than 80 peer-reviewed manuscripts and book chapters, and served as a reviewer for various international journals. Wei has given numerous presentations and served as chair/co-chair at different international conferences and symposiums.

Speakers

Almut G. Winterstein FISPE, University of Florida, USA

Almut Winterstein is professor and chair of pharmaceutical outcomes and policy and director of the Center for Drug Evaluation and Safety, both at the University of Florida. She received her pharmacy degree from the Friedrich Wilhelm University in Bonn, Germany and her PhD in Pharmacoepidemiology from the Charité Humboldt University in Berlin, Germany. As recognized expert in drug safety, she has chaired the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee from 2012-2018. Recognizing her contributions to the field of pharmacoepidemiology, Dr. Winterstein was inducted as a fellow of the International Society of Pharmacoepidemiology (IPSE) in 2013 and as president-elect of the society in 2018. In 2017, she was named the Dr. Robert and Barbara Crisafi Chair for Medication Safety in recognition of her research on drug safety and on assessing and devising ways to improve medication use. Her work in this area has resulted in more than 300 peer-reviewed publications and 21 PhD graduates in pharmacoepidemiology.

Nancy Santanello FISPE, Consultant, USA

Nancy Santanello is a physician-epidemiologist trained in Emergency Medicine and Preventive Medicine with a MS in Epidemiology. Dr. Santanello was a Medical Officer with the National Heart, Lung, and Blood Institute (NHLBI) Prevention and Demonstration Research Branch of the Division of Epidemiology and Clinical Applications (1987-1991) conducting clinical trials, epidemiology studies and developing physician training and patient education materials. She joined Merck & Co. Inc. (MSD) where she became the Vice President and Head of the Epidemiology Department (2003-2015).

Dr. Santanello consults in drug and vaccine pharmacoepidemiology (safety and effectiveness), clinical outcome assessments, and the development and validation of patient reported outcome (PRO) measures for use in clinical trials, trial and observational study design. She is a Past President of the International Society for Pharmacoepidemiology (ISPE) and is a Fellow of ISPE (FISPE). Dr. Santanello is the current Chair of the PhRMA Foundation Health Outcomes Advisory Committee.

Currently, Dr. Santanello is co-leading an ISPE working group of researchers from FDA, EMA, pharmaceutical companies and academia in an effort to incorporate real-world data in clinical trial programs as external controls.

Koji Kawakami, Kyoto University, Japan

Koji Kawakami, MD, PhD is Professor and Chair of Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyoto University. After the residency training in head and neck surgery and emergency medicine, Dr. Kawakami served as postdoc and later promoted to clinical trial IND reviewer at the US-FDA during 1999-2004. From 2006, Dr. Kawakami moved to Kyoto University, where he is conducting various clinical epidemiology and pharmacoepidemiology research programs. He is also focusing on the development of the EMR-derived clinical real world data database (currently 1.9M patients from 170 hospitals) and the health checkup database of 0-14 years old (currently from 135 local governments) in Japan.