ACPE/JSPE2019

ISPE's 12th Asian Conference on Pharmacoepidemiology

11-13 October 2019 Kyoto, Japan

Symposium 7: Real World Evidence to support new drug approval and label expansion

Moderator

K. Arnold Chan FISPE, National Taiwan University, Taiwan

Dr. Chan is a physician epidemiologist with more than 30 years of global research experience in academia and private sector, with a primary focus on post-marketing evaluation of medical products. He received medical training at National Taiwan University (MD-equivalent, 1987) and advanced training in epidemiology at Harvard School of Public Health (Doctor of Science, 1992). He has served on the faculty at National Taiwan University (NTU) and Harvard School of Public Health and joined the private industry in 2005, subsequently became Chief Scientist of the Epidemiology Unit at Optum.

Dr. Chan returned to NTU in 2013 and is currently a professor at NTU College of Medicine and Director of the NTU Health Data Research Center. In addition to scientific research, he has provided consultation for Taiwan Food and Drug Administration and related health authority for more than 20 years. Dr. Chan has authored or co-authored more than 100 peer-reviewed articles and co-edited one of the two widely used English textbook on pharmacoepidemiology.

Speakers

Jeff Lange, Amgen Inc., USA

Jeff is an epidemiologist within Amgen's Center for Observational Research. He received his PhD from the University of Iowa. During his 8 years at Amgen, he has been applying the use of observational research for both clinical development and regulatory decision-making within the therapeutic areas of oncology and general medicine. Currently, Jeff is supporting further development of organizational capabilities within Asia.

Yuki Ando, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Dr. Yuki Ando is a Senior Scientist for Biostatistics of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. She received a master's degree in Engineering from Tokyo Science University, and PhD in Health Science from Osaka University. In 1997, she joined the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC), which was established that year and subsequently transformed into the current PMDA. Currently she is responsible for the biostatistics review and consultation in the new drug and device review offices in PMDA. Additionally, she works for Office of Advanced Evaluation with Electronic Data, the office which is responsible for the use of patient level electronic study data that are submitted with new drug applications. She is responsible for promoting implementation of data standards and the use of submitted electronic study data in PMDA.

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.

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