Symposium 9: Real World Evidence for decision making: Where we are in the Asia Pacific region?

Moderator

Kiyoshi Kubota FISPE, NPO Drug Safety Research Unit Japan, Japan

Dr. Kiyoshi Kubota is a physician and a pharmacoepidemiologist. From 1991 to 1996 he worked at the Drug Safety Research Unit in England. He was Associate Professor (till 2008) and Professor (after 2008) of Department of Pharmacoepidemiology in Tokyo University from 1996 to 2014. He has been a member of the International Society for Pharmacoepidemiology (ISPE) since 1995. He worked as an Executive Committee Member of ISPE between 2015 August and 2018 August including 1 year between 2016 and 2017 when he was President of ISPE. He has been President of Japanese Society for Pharmacoepidemiology (JSPE) since 2008. He organized the ISPE's 2nd Asian meeting in 2007 and the 5th Asian meeting in 2010 in Tokyo as the congress chair. He has been an associate editor of Pharmacoepidemiology and Drug Safety, the official journal of the ISPE since 2010. He is currently President of NPO Drug Safety Research Unit Japan where he has been working since 2001.

Speakers

Solomon Iyasu, MSD, USA

Dr. Iyasu joined Merck and Co. in August of 2015 as Vice President and Global Head of Pharmacoepidemiology, Center for Observational and Real-World Evidence (CORE). He leads that department that is responsible for the design and conduct of postapproval observational safety and effectiveness studies of pharmaceutical products, real-world data analytics to characterize disease epidemiology, inform clinical trial design and clinical endpoint strategy. He also plays a key role in supporting initiatives to foster patient focused medical product development and to analyze health related big data to produce medical evidence for decision making by policy makers. He serves on Merck's Patient Innovation Council, the Safety Review Committee and the steering committees for CORE's Strategic Research Partnerships with Harvard DBMI, Karolinska Institute, and Meccabi Healthcare. Externally, he serves on the steering committee of the Reagan Udall Foundation's Innovations in Medical Evidence Development. Prior to joining Merck, Dr. Iyasu served as the Director of the Office of Pharmacovigilance and Epidemiology (OPE), in the Center for Drug Evaluation and Research (CDER) at the USFDA. During his 13-year USFDA career, he is credited with building CDER's regulatory epidemiology program and vastly increasing the role of epidemiological data in regulatory decision making regarding drug safety. Additionally, he greatly enhanced CDER's epidemiology infrastructure and expertise to enable full support of the FDA's Sentinel Initiative, the largest distributed healthcare data analytics infrastructure in the US. Prior to the USFDA, he served at the US Centers for Disease Control and Prevention (CDC) leading reproductive, perinatal and reproductive health

epidemiology and outcomes studies. He has published many research papers and book chapters pertaining to pharmacoepidemiology, pharmacovigilance, regulatory policy, and population health, perinatal and reproductive health. Dr. Iyasu received his medical training at the University of Delhi, India and his Master of Public Health at the Johns Hopkins University and a Preventive Medicine Residency at the CDC in Atlanta, Ga, USA.

Byung-Joo Park FISPE, Seoul National University College of Medicine, Korea

Byung-Joo Park graduated from Seoul National University College of Medicine at Feb 1980. He received his MPH degree from the School of Public Health at Seoul National University at Feb 1982. And he received his PhD of Epidemiology at Seoul National University at Feb 1984. He is current Professor at Department of Preventive Medicine at Seoul National University College of Medicine. He had been in charge of Head of Division of Pharmacoepidemiology in Clinical Trial Center at Seoul National University Hospital for 11 years since 1997. He founded the Medical Research Collaborating Center at Seoul National University College of Medicine & Seoul National University Hospital and served as the first Director from Mar 2004 to Jun 2013. He has attended ICPE every year since 1993 and became a member of the Board of Directors representing Academia. He has been serving as the President of Korea Public Health Association since Dec 2014. He served as the Chairperson of the Policy Development Committee of the National Academy of Medicine of Korea from Jan 2016 to Jan 2019 and was elected as the Vice President at Jan 2019.

Daniel J. Ruzicka, MSD KK, Japan

Dr. Daniel J. Ruzicka is a trained cardiac-thoracic surgeon and has more than 15 years of experience in healthcare. Daniel holds a PhD in Occupational and Environmental Health of the Ludwig-Maximillians-University of Munich and a Master of Science in Medical Engineering of the Technical University of Munich, Germany. After his clinical work at the German Heart Center in Munich, where he was responsible for patients with heart diseases, he started his career in the medical device industry with Siemens Healthineers and held various positions in Product management and Marketing with global responsibilities as well as positions locally in Japan.
Daniel joined the pharmaceutical industry at MSD as a Medical Advisor and is currently leading the Acute Care and Hospital franchise in Medical Affairs as Executive Director.
In this responsibility he is in charge of the overall medical strategy of the franchise, which includes liaison with scientific leaders for insights collection and understanding latest medical trends, medical education and datageneration. He is personally involved in various datageneration projects around real-world data and evidence (RWD/RWE).
Daniel is also involved in an industry wide working group of PhRMA Japan around RWD/RWE.

Yoshiaki Uyama, Pharmaceuticals & Medical Devices Agency, Japan

Yoshiaki Uyama is currently Office Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals & Medical Devices Agency (PMDA) of Japan. He is responsible for all epidemiological activities in PMDA including the projects of MIHARI(Medical Information for risk assessment initiative) and MID-NETⓇ(Medical Information Database Network). He has many experiences in regulatory science of benefit/risk assessment of a new drug, including the role in ICH as ICH Technical Coordinator (2004-2009), the topic leader of ICH E15 and E16, Rapporteur of ICH E17 Expert Working Group (2014-). He is also served as the visiting professor in Nagoya University (Graduate School of Medicine) and Chiba University (Graduate School of Medicine).