Symposium 8: Post-market surveillance of medicines, vaccines and medical devices across the Asia-Pacific region: The next 10 Years

Moderators

Edward Chia-Cheng Lai, National Cheng Kung University, Taiwan

Dr. Edward Lai is an Assistant Professor for School of Pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Sciences, at National Cheng Kung University in Taiwan. His research interests include drug safety, comparative effectiveness and international multi-databases pharmacoepidemiologic studies. He was a chair of the Asian Pharmacoepidemiology Network, and currently works on international projects for psychiatric medications, biologic agents as well as oncologic treatments. He receives governmental grants for developing pharmacoepidemiologic and analytic methods to protect data privacy for multiple databases studies. He is also working with Taiwan Drug Relief Foundation to improve drug safety, signal detection and post-marketing surveillance using electronic healthcare databases.

Nam-Kyong Choi, Ewha Womans University, South Korea

Nam-Kyong Choi is an Associate Professor of the Department of Health Convergence, College of Science & Industry Convergence at Ewha Womans University in Seoul, South Korea. She received her B.S. in Pharmacy from Ewha Womans University and M.Sc. and Ph.D. in Pharmacoepidemiology from the Seoul National University College of Medicine. She had been worked as a Visiting Professor in the Division of Pharmacoepidemiology Pharmacoeconomics, within the Department of Medicine at Brigham and Women's Hospital and Harvard Medical School from 2015 to 2017.

She is a chair-elect of Asian Pharmacoepidemiology Network (AsPEN), a director of the International Cooperation Committee in Korean Society for Pharmacoepidemiology and Risk Management, and a member of Editorial Board in Korean Academy of Social & Managed Care Pharmacy. She has been an associate editor of Pharmacoepidemiology and Drug Safety, the official journal of ISPE since 2010. She is Advisory Committee Members of the Drug Safety Evaluation and the Social Relief Scheme for Serious Adverse Drug Reactions for the Korea Institute of Drug Safety and Risk Management.

Her area of research focuses on the development and application of epidemiologic and statistical methods for evaluating the safety and comparative effectiveness of medical products in large health databases.

Kenneth Man, University College London, UK; University of Hong Kong, Hong Kong

Kenneth is currently a Maplethorpe Fellow at the Research Department of Practice and Policy, UCL School of Pharmacy, London. He is also current chair of Asia Pharmacoepidemiology Network (AsPEN), a collaborative network on medication safety and pharmacoepidemiology research across the Asia-Pacific region. With expertise in medication research with electronic health care databases and novel epidemiological methodologies, his work encompassed research in Paediatric and Psychiatric Pharmacoepidemiology in particular treatment for neurodevelopmental disorders. He receives the CW Maplethorpe Fellowship in Pharmacy to investigate the safety of psychotropic medications use in pregnancy.

Speakers

Nam-Kyong Choi, Ewha Womans University, South Korea

Nam-Kyong Choi is an Associate Professor of the Department of Health Convergence, College of Science & Industry Convergence at Ewha Womans University in Seoul, South Korea. She received her B.S. in Pharmacy from Ewha Womans University and M.Sc. and Ph.D. in Pharmacoepidemiology from the Seoul National University College of Medicine. She had been worked as a Visiting Professor in the Division of Pharmacoepidemiology Pharmacoeconomics, within the Department of Medicine at Brigham and Women's Hospital and Harvard Medical School from 2015 to 2017.
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Ju-Young Shin, Sungkyunkwan University, South Korea

Dr. Ju-Young Shin is a current assistant professor at school of pharmacy, SungKyunKwan University (SKKU). She also serves as an associate editor of Pharmacoepidemiolgoy and Drug Safety (PDS). She received her B.S. in pharmacy from Seoul National University, MPH in health policy and Ph.D. in pharmacoepidemiology from the Seoul National University College of Medicine. She was a visiting fellow at university of South Australia, and postdoctoral fellow at McGill University. She published more than 90 peer-reviewed journal and published her study in British Medical Journal (BMJ), twice, regarding the safety of antidepressants and ADHD medication using 50 million Korean healthcare database. Her area of research is a safety of psychotropic drugs, vaccine safety, methodology development, and drug utilization review in the frail population. She is leading or co-leading several projects sponsored by Korea Ministry of Food and Drug Safety, Ministry of Health and Welfare, Center for Disease Control and Prevention, National Research Foundations, and Pharmaceutical companies. She was a past-team director at Korea Institute of Drug Safety and Risk Management (KIDS) and led several epidemiological studies. She is now in charge of vice-director in one of Korean regional pharmacovigilance center- pharmacist association. She also

serves as a consultant for several Korean governmental committee including national evidence-based collaborating agency (NECA), and KIDS. She has been a member of International Society for Pharmacoepidemiology (ISPE) since 2007, and is currently a member of board of directors of Korea society of Pharmacoepidemiology and Risk Management (KoPERM), Korea society of epidemiology, and Korea academy of social and managed care pharmacy.

Nicole Pratt, University of South Australia, Australia

Dr Nicole Pratt is an Associate Professor and Deputy Director of the Quality Use of Medicines and Pharmacy Research Centre, Sansom Institute, University of South Australia. She is a member of the Drug Utilisation Subcommittee (DUSC) of the Australian Department of Health Pharmaceutical Benefits Advisory Committee (PBAC). Nicole leads the evaluation of the Department of Veterans Affairs, Veterans' Medicines Advice and Therapeutics Education Service (Veterans' MATES) program which uses administrative claims data to develop and evaluate interventions to improve use of medicines in the veteran population in Australia. She is a past-chair of the Asian Pharmacoepidemiology Network (AsPEN) initiative (www.aspennet.asia) and a collaborator of Observational Health and Data Sciences and Informatics (www.ohdsi.org) which aims to bring out the value of health data through large-scale analytics.

Gianluca Trifirò, University of Messina, Italy

Gianluca Trifirò is MD, with Post-Gaduation Degree in Clinical Pharmacology (University of Messina, Italy), Master of Science in Clinical Epidemiology (NIHES, NL) and PhD in Pharmacoepidemiology (Erasmus Medical Center, Rotterdam, NL). Associate Professor of Pharmacology (with qualification for Full professor) and Clinical Pharmacologist at the Academic Hospital of Messina. Scientific coordinator of an Academic Master program on "Use of Real-world data for evaluations in Pharmacovigilance, Pharmacoepidemiology and Pharmacoeconomics" at University of Messina.
Clinical pharmacologist of Phase I Clinical Trial Unit of Bambino Gesù Pediatric Hospital of Rome (Italy).
Member of editorial board of Drug Safety and Pharmacoepidemiology and Drug Safety. Member of Steering Group of European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) at the European Medicine Agency. Chair of the Working Group (WG) on methodological approaches for multisource studies of ENCePP. Chair of the Local Organizing Committees for the mid-year meetings of ISPE (Florence, April 2011; Rome, April 2019) and component of Local Organizing Committee of the International Society of Pharmacovigilance annual meeting (Pisa, 2013). Chair of the Biologics/Biosimilar Special Interest Group of ISPE. Member of Scientific Committee of Pharmacovigilance Office of Italian Drug Agency; chair of Italian Society of Pharmacology WG on Pharmacovigilance and Pharmacoepidemiology.

Mary-Beth Ritchey FISPE, RTI Health Solutions, USA

Mary Beth Ritchey is the Director, Epidemiology, Medical Devices & Real-World Evidence at RTI-HS. In her role, Dr. Ritchey performs and oversees the scientific, technical, and logistic aspects of projects, including conduct of prospective and retrospective non-interventional safety, effectiveness, and utilization studies; registry governance and implementation; assessment of the regulatory landscape and study portfolio planning for novel therapeutics and rare diseases; and consultation on timing, design, and practical application of methods for real-world studies. Prior to joining RTI-HS, Dr. Ritchey's career spanned government and industry. During

her tenure at the US FDA, she managed the device Postmarket Surveillance Studies program and was involved with the Medical Device Epidemiology Network and Sentinel initiatives. At Merck, she developed data strategy tools, collaborations, and a continuous learning organization for Comparative and Outcomes Evidence. At Procter & Gamble, she enhanced the signal and risk management programs to include synthesis and interpretation across multiple disparate data sources. She obtained her masters and doctorate degrees in Epidemiology from the UNC Gillings School of Global Public Health and holds an adjunct faculty appointment in the Center for Pharmacoepidemiology and Treatment Science at Rutgers University.