Symposium 5: Use of real-world evidence (RWE) in regulatory decision-making: Regulatory guidance and examples from Asia and the US

Moderator

Darren Toh FISPE, Harvard Medical School and Harvard Pilgrim Health Care Institute, USA

Darren Toh, ScD is an Associate Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is a pharmacoepidemiologist with an interest in the comparative safety and effectiveness research of medical products. His research focuses on 1) assessing the risks and benefits of medical products using electronic data collected as part of routine healthcare delivery, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks. Darren is Associate Director of the Therapeutics Research and Infectious Disease Epidemiology (TIDE) group in the Department of Population Medicine. He is also Chief Scientist at the Operations Center of the FDA-funded Sentinel System, a congressionally mandated national medical product safety surveillance system. Darren received his doctoral degree in Epidemiology from the Harvard School of Public Health.

Speakers

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Jeremy Rassen, Aetion, Inc., USA

Jeremy A. Rassen, MS, ScD is a pharmacoepidemiologist with 25 years of academic and industry experience. He is co-founder, president, and chief science officer at Aetion, a health care technology company that delivers real-world evidence for life sciences companies, payers, and regulatory agencies. Prior to founding Aetion, Dr. Rassen was Assistant Professor of Medicine at Harvard Medical School, where he focused on methods to improve the quality and validity of real-world data studies. He also worked in Silicon Valley in a variety of tech companies. Dr. Rassen received his bachelor's degree in Computer Science from Harvard College and his master's and doctorate degrees in Epidemiology from the Harvard T.H. Chan School of Public Health.

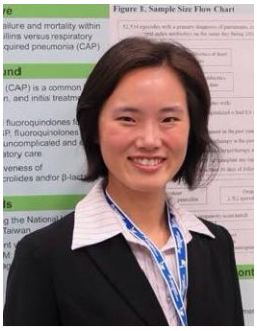
Yusuke Okada, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Mr. Yusuke Okada is a safety reviewer in the Office of Medical Informatics and Epidemiology at the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. He joined PMDA in 2015 and he had worked in office of generic drugs as a reviewer for 3 years. Then, he transferred to office of medical informatics and epidemiology. He currently reviews post marketing database study protocols and conducts pharmacoepidemiological database studies using healthcare information databases like MID-NET®. He also has experience in working for quality control of MID-NET® database.

Jasmanda Wu, Sanofi, USA and China

Dr. Jasmanda Wu is currently the Board of Director for industry/service provider for Asia-Pacific region and Chair of Rare Disease Special Interest Group for ISPE. She became the fellow of the ISPE in 2016. She has over 17 years of experience with pharmaceutical industry spanning real-world evidence generation, pharmacoepidemiology, pharmacovigilance and benefit risk assessment for activities across product life cycle.
Jasmanda is currently a Senior Director in the Real-World Evidence & Clinical Outcomes Department, as part of Global Medical within the pharmaceutical company Sanofi. In this role, she leads the development and execution of real-world research projects applying conventional and advanced epidemiological methods across a variety of therapeutic areas. Prior to that, she had expatriation assignment in Asia-Pacific Region and was based in Shanghai, China from 2015 to 2017. She served as a real-world evidence/pharmacoepidemiology expert for Asia-Pacific R&D and Regional Medical Affair team to support products in development and launches.
She obtained her doctoral degree in epidemiology from the University of Michigan Department of Epidemiology and obtained a Master of Public Health degree from the University of Texas-Houston School of Public Health.

Chi-Chuan Wang, National Taiwan University, Taiwan



Dr. Chi-Chuan (Emma) Wang, is an Associate Professor at the School of Pharmacy, National Taiwan University. Dr. Wang had her undergraduate pharmacy training from National Taiwan University, and received her Masters' degree in Health Policy and Administration from Washington State University at Spokane, and her Ph.D. degree in Pharmaceutical Outcomes and Policy at UNC Chapel Hill. Prior to joining NTU, Dr. Wang worked as a senior health economist at RTI Health Solutions. Dr. Wang has particular expertise in study design and extensive experience working on large databases, including

administrative claims data, electronic health records, and national survey data. She has published several studies evaluating the effectiveness, safety, and costs associated with pharmaceutical products. Dr. Wang's current work focuses on the integration and application of real-world data and was awarded the MOST Young Scholar Fellowship by the Ministry of Science and Technology in Taiwan in 2018.