SYMPOSIUM 3. Adequate for comparison? Global perspectives on external comparator studies in rare diseases

Moderator

Joan Largent, IQVIA, USA

Joan Largent is currently a Senior Director in IQVIA's Global Epidemiology team and has nearly 25 years of experience in the design, execution, analysis and reporting of observational and RWE research. Her experience includes designing, executing and providing scientific oversight of post-marketing regulatory commitments and voluntary non-interventional studies across multiple therapeutic areas in the US, Europe and Asia-Pacific. She has also provided strategic input to FDA advisory and device panel presentations. Her areas of expertise include registries, retrospective chart reviews, external comparator arms, direct-to-patient approaches, rollover/extensions, natural history studies, drug safety and comparative effectiveness research. Dr. Largent is an active member of ISPE and currently serves as chair of the Publications & Communications Committee. Dr. Largent started her career in academia at the University of California, Irvine, where her focus was in cancer epidemiology research and teaching epidemiology methods.

Speakers

Nao Takano, Pharmaceuticals and Medical Devices Agency, Japan

Nao Takano, M.D. and Ph.D. is a clinical reviewer of Pharmaceuticals and Medical Devices Agency (PMDA). She graduated from Miyazaki Medical University with obtaining medical license in 2004, and she has worked as a general surgeon. She learned hepato-biliary-pancreatic surgery and oncology at the department of gastroenterological surgery, Nagoya University Graduate School of Medicine, Japan, with obtaining her doctor's degree in 2017. From 2019, she has worked at PMDA as a clinical reviewer at the office of Pharmacovigilance, then she moved to the office of New Drug V and joined real world data working group from 2021.

Catherine Lerro, Food and Drug Administration (FDA), USA

Dr. Catherine Lerro, Ph.D., M.P.H. is an epidemiologist in the Oncology Center of Excellence's (OCE) Real World Evidence Program at the US Food and Drug Administration (FDA). Prior to joining the OCE, Dr. Lerro was an epidemiology reviewer and team lead in the Office of Surveillance and Epidemiology in the FDA's Center for Drug Evaluation and Research. She earned her Ph.D. from Yale in cancer epidemiology, her B.A. in public health studies from Johns Hopkins and her M.P.H. in chronic disease epidemiology from Yale. She completed a post-doctoral fellowship at the National Cancer Institute in the Division of Cancer Epidemiology and Genetics. She has also previously worked as an epidemiologist in the Surveillance and Health Services Research group at the American Cancer Society.

K. Arnold Chan FISPE, National Taiwan University, Taiwan

Dr. Chan is a pharmacoepidemiologist with more than 30 years of global research experience in academia and private sector. 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 academia in 2013 and became a professor at NTU College of Medicine. 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 150 peer-reviewed articles and co-edited a textbook on pharmacoepidemiology. His H-index is 59 according to Google Scholar as of September 2022.

Mehmet Burcu, Merck & Co Inc, USA

Dr. Mehmet Burcu is a Senior Principal Scientist in Epidemiology at Merck & Co., Inc., Rahway, NJ, United States. In his current role, he works with large, automated database studies as well as global multi-country real-world evidence (RWE) studies to support clinical development and regulatory decision making in pre-approval/post-approval settings. He has published on a wide range of epidemiology methods, drug safety, policy, and patient-centered real-world evidence topics. He received his doctoral degree in Pharmacoepidemiology at the University of Maryland, Baltimore. He also holds a B.A. in Biochemistry and an M.S. in Clinical Research and Epidemiology. He has served on the advisory board of the National Health Council projects and served in leadership roles in committees and working groups of various scientific cross-sector organizations to advance the science of epidemiology and RWE.

Gerd Rippin, IQVIA, Germany

Dr. Gerd Rippin studied statistics at the University of Dortmund, Germany until 1995 (equivalent to BSc+MSc), whereafter he worked at the Institute of Medical Statistics and Documentation at the University of Mainz, Germany, with obtaining his Ph.D. (Dr. rer. physiol.) in 1999. In the year 2000, Dr. Gerd Rippin started his career in the industry, where he worked for CRO's, as a contractor and in the pharmaceutical industry before joining the Real-World Biostatistical Department of IQVIA in 2017. Dr. Gerd Rippin is a senior leader of RW Biostatistics with now 22 years of industry experience, who has specialized in complex RW statistical methodology, including causal inference methods and advanced survival analysis techniques. He recently published with IQVIA and EMA co-authors about causal inference for external comparator arm studies.