June 9, 2023, 9am -11 am (Japan time)

Lecture: 60 minutes; Q&A: 30 minutes

JAPhMed Real World Analytics Webinar:

Fee: Free

Title: The role of statistics in HTA/RWE application

Weili He and Hongwei Wang

Medical Affairs & Health Technology Assessment Statistics, AbbVie

Abstract:

Evidence-based decision-making is essential for drug development and a continuum across all stages. This covers the internal go/no-go decision of early pipeline, the regulatory and reimbursement decision by health authorities, and life-cycle management for value demonstration. This robust evidence generation requires multidisciplinary collaboration and statistics plays a central role in fit-for-purpose study design and analytic framework selection, assessment of robustness and results interpretation. While randomized clinical trials remain the gold standard to establish efficacy and safety profile of medical products, its strict protocol specification, high cost, ethical consideration and lack of venerability to more heterogeneous patient population in routine clinical practice calls for real-world studies. In this talk, we will introduce the opportunities and challenges of leveraging real-world evidence (RWE) for more effective drug development, and highlight the importance of applying statistical principals and causal inference methodologies in such research endeavor. Specifically, in preparation for the regulatory and reimbursement decisions, clinical trials with external control using historical data, real-world studies quantifying natural history of disease under standard of care, network meta-analysis synthesizing direct and indirect evidence, and populate scenarios for economic modeling are some examples. After initial regulatory approval, real-world studies to support label expansion, fulfill regulatory commitments, generate treatment usage pattern and comparative effectiveness are important components of the holistic evidence planning. Statisticians with in-depth understanding of real-world data sources, methodology to account for the inherent confounding and bias, advanced analytics for predictive modeling and complex data will be your important research partners.

[Speakers]

Weili He

Dr. Weili He has over 25 years of experience working in the biopharmaceutical industry. She is currently a Distinguished Research Fellow and head of Medical Affairs and Health Technology Assessment statistics at AbbVie. She has a PhD in Biostatistics. Weili's areas of expertise span across clinical trials, real-world studies and evidence generations, statistical methodologies in clinical trials, observational research, innovative adaptive designs, and benefit-risk assessment. She is the lead or co-author of more than 60 peer-reviewed publications in statistics or medical journals and lead editor of two books on adaptive design and benefit-risk assessment, respectively. She is the co-founder and co-chair of the American Statistical Association (ASA) Biopharmaceutical Section (BIOP) Real-world Evidence Scientific Working Group from 2018 to 2022. She is also the Fonder and Co-chair of a newly formed ASA BIOP HTA Scientific Working Group. Weili is the BIOP Chair-Elect, Chair, and Past Chair from 2020-2022. She serves as an Associate Editor of Statistics in Biopharmaceutical Research since 2014, and is an elected Fellow of ASA since 2018.

Hongwei Wang

Dr. Hongwei Wang is currently a Director of Medical Affairs & Health Technology Assessment Statistics and Research Fellow at AbbVie. He has a PhD in Statistics from Rutgers University and close to 20 years of industry experience in evidence planning and generation. His research interests include designing and analyzing real-world studies, network meta-analysis and advanced analytics. Before joining AbbVie in Jun 2017, he worked at Merck and Sanofi.

[Chair / Discussant]

Toshifumi Sugitani

Dr. Toshifumi Sugitani is currently a Director of RWE at Syneos Health Japan. He has a PhD in Biostatistics. Toshi's area of expertise span across statistical methodologies in confirmatory clinical trial designs (e.g., Graphical approaches, Adaptive designs), dose-response studies (e.g, MCP-Mod), observational studies, real-world studies and evidence generation using large healthcare databases in Japan (e.g, MDV, JMDC, C-CAT), patient-preference studies, and marketing science for sales data in pharma industry in Japan (e.g., time-series analysis using state-space modelling). He is the lead or co-author of more than 20 peer-reviewed publications in statistics or medical journals and the co-author of a book chapter of "Multiple comparison" in 2nd edition of International Encyclopedia of Statistical Science (in press). He received a Research Encouragement Award from the Biometric Society of Japan in 2020.