ASA Biopharmaceutical Section

ASA Safety Working Group Quarterly Scientific Webinar – Q4 2025

The **Safety Scientific Working Group** is sponsored by the Biopharmaceutical section of the American Statistical Association. The mission of the working group is to empower interdisciplinary safety management partnerships between the biostatistics community, epidemiologists and clinical scientists to better enable qualitative and quantitative safety evaluation throughout the drug development life cycle.

In the 2025 Q4 scientific webinar, we are presenting **Reimagining Drug Safety with AI: A Quantitative Leap Forward Part 2** on **October 7 (11:00-12:30 EST)**. The scientific webinar is free. No registration is required. Please add the meeting info to your calendar.

Topic: Reimagining Drug Safety with AI: A Quantitative Leap Forward (Part 2)	
11:00 – 11:05	**Opening/Introduction** **Moderator:** *Lian Lin, Scholar Rock*
11:05 – 11:30	**Title:** AI in FDA's post-marketing drug safety monitoring **Speaker:** *Yong Ma, US FDA*
11:30 – 11:55	**Title:** AI for design and analysis real-world study **Speaker:** *Xiaoyan Wang, Tulane University*
11:55 – 12:25	**Panel Discussion** *Robert (Bob) Ball, US FDA* *Walter Straus, Moderna* *William Wang, Merck*
12:25 - 12:30	**Closing remarks**

Abstract:

In the effort to better promote public health and protect patient safety, there is growing interest in developing a systematic approach for the safety evaluation of pharmaceutical products, not only for post-marketing safety surveillance, but also for pre-marketing safety monitoring. With the increasing volume and complexity of clinical trials and post-marketing safety data, the landscape of drug safety is rapidly evolving, demanding innovative approaches. As artificial intelligence (AI) and Machine Learning (ML) continue to evolve and advance biomedical research, their increased integration in and impact on PV practice are inevitable.

In recent years, there have been many promising use cases of AI/ML enhancing the efficiency, accuracy, and timeliness of drug safety evaluation. With AI, the analytical capability is empowered. However, the implementation of AI/ML presents several significant challenges. These include ensuring data privacy and security, mitigating model bias, establishing robust model validation processes, navigating complex ethical implications, and developing clear, globally harmonized regulatory standards. Biostatisticians and other quantitative scientists can closely engage with Pharmacovigilance, clinical, and regulatory scientists and play a vital role in these efforts.

In this 3-part webinar series, Part 1 will explore the transformative potential of AI in enhancing safety assessments across critical domains. The first presentation will highlight the role of AI agents in quantitative safety evaluation, showcasing two pioneering studies that leverage advanced AI techniques to improve safety assessment. The second presentation will focus on the integration of AI in clinical trial Data Monitoring Committees (DMCs), demonstrating how AI-driven approaches can optimize decision-making and ensure patient safety. The third presentation will provide another use case of how AI can be leveraged for safety signal casualty assessment.

In part 2 of this webinar series, we will showcase a few studies involving AI conducted by the FDA in the post-marketing setting. These include the use of NLP tools in pharmacovigilance to extract demographic information from the narrative filed of FDA's Adverse Event Reporting System (FAERS), de-duplicate reports from FAERS, identify outcome and covariates from electronic health records, and obtain real-time information from social media in time of public health emergency. The second presentation will focus on the AI tools for designing and analyzing real-world study. AI is increasingly being utilized to enhance the design and execution of observational studies in clinical research. In addition, AI can significantly improve the efficiency and accuracy of these studies by automating various aspects of the research process. Multiple use cases will be discussed.

Presentation 1: AI in the FDA's post-marketing drug safety monitoring

Speaker: Yong Ma, US FDA

This presentation showcases several natural language processing (NLP) applications within FDA's post-marketing surveillance from 2018 to present, demonstrating evolution from rule-based algorithms to sophisticated language models across pharmacovigilance, pharmacoepidemiology, and public health emergency response. In pharmacovigilance, NLP achieved high accuracy extracting missing demographics from FAERS and excellent sensitivity/specificity in duplicate report identification, while pharmacoepidemiology applications significantly improved anaphylaxis identification in electronic health records and extracted outcomes from millions of clinical notes in the MOSAIC-NLP project. During COVID-19, BERT-Large models demonstrated strong performance identifying cases from Reddit posts and extracted patient-reported symptoms aligning with CDC trends. These implementations demonstrate NLP's transformative potential in regulatory science, enabling automated extraction of clinically relevant information while highlighting current technology capabilities and limitations.

Dr. Yong Ma is a Lead Mathematical Statistician in the Division of Biometrics VII, Office of Biostatistics, CDER, FDA. She leads a review team supporting post-market safety studies and over-the-counter drug applications. Dr. Ma joined the FDA in 2015 as a statistical reviewer and specializes in methodologies tailored for post-market safety studies, including propensity score methods, causal inference, machine learning and natural language processing. Prior to joining the FDA, she served as an Assistant Research Professor at George Washington University. Dr. Ma brings over 25 years of experience in statistical analysis and research and she has co-authored more than 50 peer-reviewed publications. Dr. Ma has also been an active member of the ASA safety working group, work stream 3 since 2016.

Presentation 2: AI for design and analysis real-world study

Speaker: Xiaoyan Wang, Tulane University

Abstract:
Artificial intelligence (AI) and real-world data (RWD) are transforming how evidence is generated and applied across drug development and commercialization. This presentation will highlight key applications of AI in scientific literature, social listening, and clinical research.
In literature and evidence synthesis, natural language processing accelerates reviews and horizon scanning to inform regulatory and HTA submissions. Social listening and digital data mining capture patient and caregiver perspectives, offering unique insights into unmet needs and treatment experiences. In clinical trials, AI and RWD integration enhance site selection, recruitment, endpoint development, and the use of external control arms, improving trial efficiency and relevance.
Finally, we will consider commercialization and market access, where AI-enabled analytics inform payer engagement, patient journey mapping, and post-market evidence. The session will also address transparency, validation, and emerging best practices such as the ELEVATE-AI guidelines to ensure responsible adoption.

Dr. Xiaoyan Wang is a professor at Department of Health Policy and Management of Tulane University and Chief Scientist of IMO Health. She is a leading researcher in biomedical informatics and health economics, with extensive expertise in applying AI and large language models to transform healthcare, life sciences, clinical development and drug commercialization. She has authored hundreds of publications and led many innovations and the guidelines for evaluating LLMs in HEOR, HTA and drug development. She was recently CSO of Melex and VP of Healthcare Analytics and Informatics at GeneDx. She was a faculty member at the University of Connecticut, UConn Health Center, and Mount Sinai Health Systems bridging research, health services, and teaching. She holds a Ph.D. in Biomedical Informatics and NLP from Columbia University School of Medicine.

Dr. Robert Ball, MD, MPH, ScM is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research, Food and Drug Administration (FDA) where he shares in responsibilities leading OSE in the premarket and postmarket regulation of drugs and therapeutic biologics through adverse event surveillance, pharmacoepidemiology, risk management, and medication error prevention. His recent research has included the application of artificial intelligence to improve the evaluation of medical product safety and effectiveness in electronic healthcare data systems.

Dr. Walter Straus is Vice President and Distinguished Vaccine Safety Physician at Moderna, where he oversees vaccine safety for the company's vaccine pipeline. Prior to joining Moderna, Dr. Straus was an Epidemic Intelligence Officer before joining the permanent staff at the Centers for Disease Control and Prevention (CDC, Atlanta). He then worked for 20 years at Merck & Co. Inc. where he led teams in scientific affairs, epidemiology, and clinical safety and risk management, primarily supporting the vaccine and infectious disease portfolio. He has contributed to the development and or post-authorization assessment of numerous small molecules and vaccines, and has presented and published widely, particularly in drug/vaccine safety, pharmacoepidemiology, and bioethics. He is a Fellow of the College of Physicians of Philadelphia (FCPP) and of the American College of Physicians (FACP). He is a member of the WHO/CIOMS Working Group on Artificial Intelligence in Pharmacovigilance, and has previously contributed to CIOMS working groups on DILI and on vaccine safety surveillance.

Dr. William (Bill) Wang is the Executive Director in the Department of Biostatistics and Research Decision Sciences (BARDS) at Merck Research Laboratories (MRL). He has over 30 years of experience working in the pharmaceutical industry, including 25 years at MRL, Merck & Co., Inc. He has extensive experience in clinical trial design, analysis/reporting, and regulatory filings across multiple therapeutic areas. During his tenure at MRL, Bill led the design and build-up of MRL's global biometrics operations in the Asia-Pacific region and spearheaded the establishment of the Clinical Safety Statistics group.
Dr. Bill Wang has served as the deputy topic leader for the ICH E17 working group on simultaneous global drug development. He has played a leading role in the establishment of the American Statistical Association (ASA) Safety Working Group (SWG). Dr. Bill Wang has co-edited two books: "Multi-Regional Clinical Development After E17" (Chapman Hall, 2021) and "Quantitative Drug Safety and Benefit-Risk Evaluation" (Chapman Hall, 2021). He was elected as a Fellow of the American Statistical Association in 2018.

Dr. Lian Lin is the Senior Director of Medical Affair Statistics at Scholar Rock. Before joining Scholar Roack, he was a Director/Head of Safety Statistics at Moderna and Biostatistician at Merck following the completion of his PhD at The University of Texas. His research interests encompass Adaptive Trial Design, Causal Inference, Evidence Synthesis, Survival Analysis, and Bayesian Analysis. In recent years, Lian has been actively involved in developing innovative tools for clinical trial data processing, analysis, reporting, and visualization. He is an active member of the ASA Safety Working Group and co-leads the initiative on integrating RCT and RWE for safety decision-making.