ASA Biopharmaceutical Section

ASA Safety Working Group Quarterly Scientific Webinar – Q3 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 this 2-part webinar series for the 2025 Q3 webinar, Part 1 is **Reimagining Drug Safety with AI: A Quantitative Leap Forward** on **September 9 (11:00-12:30 EDT)**. It 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 on **October 7 (11:00-12:30 EDT)**, we will showcase a few studies involving AI conducted by the FDA in the post-marketing setting. These include use of NLP tools in pharmacovigilance to extract demographic information from the narrative field 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.

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 1)	
11:00 – 11:05	**Opening/Introduction** **Moderator:** *Lian Lin, Scholar Rock*
11:05 – 11:25	**Title:** AI Agents in Quantitative Safety Evaluation **Speaker:** *Wei Wang, Merck*
11:25 – 11:45	**Title:** Leveraging Opensource Tools, Artificial Intelligence, and Large Language Models to Enhance DMC Data Packages **Speaker:** *Melvin Munsaka, AbbVie*
11:45 – 12:05	**Title:** AI Automating Multimodal Evidence Integration for Drug Safety Signal Causality Assessment **Speaker:** *Sue Lee, Takeda*
12:05 – 12:25	**Panel Discussion** *James Buchanan, Covilance* *Judy Li, AstraZeneca* *Tarek Hammad, Takeda*

ASA Biopharmaceutical Section

12:25 - 12:30	**Closing remarks**
Meeting Information	**Meeting ID: 869 9441 1032** **Passcode: 123456** **Click here to join the meeting**

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 pharmacovigilance (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.

Presentation 1: AI Agents in Quantitative Safety Evaluation

Speaker: Wei Wang, Merck

This presentation explores the role of AI agents in advancing quantitative safety evaluation through two innovative studies. The first study (arXiv:2407.19118) introduces a framework that enhances safety evaluations by integrating causal inference with AI agents to model cause-effect relationships, emphasizing methodological advancements and theoretical contributions. The second study (arXiv:2408.01869) presents MALADE, a multi-agent system leveraging large language models (LLMs) and retrieval-augmented generation (RAG) to extract adverse drug events from pharmaceutical data, effectively managing terminological variations and narrative complexity. Together, these studies illustrate how AI agents improve the precision, scalability, and reliability of safety evaluations across diverse applications.

Dr. Wei Wang is an Associate Principal Scientist of Biostatistics in the Clinical Safety Statistics group at Merck. He earned his PhD in Biostatistics from Rutgers University in 2020. Since joining Merck in September 2020, he has led safety statistics for several oncology programs, supporting internal aggregate safety evaluations and regulatory requests. His research focuses on assessing treatment effects on drug safety via causal inference, addressing statistical challenges like competing risks and informative censoring. Additionally, he leads a task force on causal inference within the ASA Biopharmaceutical Section Safety Scientific Working Group.

Presentation 2: Leveraging Opensource Tools, Artificial Intelligence, and Large Language Models to Enhance DMC Data Packages

Speaker: Melvin Munsaka, AbbVie

Data Monitoring Committees (DMCs) are responsible for a variety of tasks, including ongoing formal and informal evaluations of participant safety through review of adverse events, and other safety signals that may arise during the conduct of a trial. A big challenge DMCs face is the sheer volume of the data package (tables, listings, and figure outputs) which makes it difficult to conduct a thorough review and is likely to increase the likelihood of critical insights or trends being missed or overlooked. Manual searches of clinical trial data risk missing crucial information and hinder thorough analysis, affecting the DMC's ability to make timely decisions. A purposeful data package should assemble relevant information in a way that supports the DMC's decision process. Additionally, it has been repeatedly argued that DMC data packages need an overhaul in terms of outputs, organization, structure, along with leveraging modern available opensource tools that allow for faster generation of DMC packages and a variety of delivery modalities for efficient and timely data insights. This can include functionality for interactivity, drill down, and use of emerging technologies including artificial intelligence and large language models. This discussion will focus on the development of DMC data packages leveraging opensource tools, artificial intelligence, and large language models.

Presentation 3: AI Automating Multimodal Evidence Integration for Drug Safety Signal Causality Assessment

Speaker: Sue Lee, Takeda

The safety signal assessment process evaluates the potential causality association between a given product and a particular adverse event from multiple data sources. While regulators often require pharmaceutical companies to use a structured approach for assessing the causality of their products, the available methods are challenged by a number of procedural differences, even when drawing from the same domain of elements and substantial number of manual analyses. To mitigate these inconsistencies in assessing causality, the Hammad-Afsar Framework was developed which proposed a holistic framework for causality assessment that utilized a combination of expert judgment/global introspection, evidence-based medicine, and probabilistic methods.

Additionally, a holistic ecosystem for signal assessment was designed as a proof of concept called *SCOPE* to create an AI-driven, integrated safety platform which uses multimodal evidence integration and weighted probabilistic approaches (integration of the Hammad-Afsar framework), to automate and support confirmation of drug safety signals. This has the potential to provide more consistent, streamlined, and automated methodologies for signal assessment enhancing efficiency, accuracy, and standardization.

Dr. Sue Lee is the Director of Signal Management and Innovation at Takeda and comes with a diverse background in drug discovery, clinical, and pharmacovigilance. She received her Ph.D. in Medicinal Chemistry and Pharmacognosy at the University of Illinois at Chicago and quickly shifted into drug safety. Sue has co-published multiple publications and have presented at global conferences. In her current role

at Takeda, she focuses on elevating the signal management process and promote efficiencies through the integration of AI/ML and digital technologies.

Dr. James Buchanan is presently an independent drug safety consultant. He graduated from the University of California, San Francisco with a PharmD degree in clinical pharmacy. He worked in the area of clinical toxicology at the Bay Area Regional Poison Control Center at San Francisco General Hospital before entering the pharmaceutical industry. Dr. Buchanan began his industry career at Genentech where he worked for 9 years in the areas of medical information and drug safety in the clinical development department. He subsequently moved to Gilead Sciences to establish a drug safety department. After leaving Gilead Sciences, Dr. Buchanan started the drug safety department at Tularik Inc where he acted as Chief Safety Officer until the company was acquired 5 years later by Amgen. Following the merger with Amgen, he moved to Nuvelo to establish a drug safety department and act as Chief Safety Officer where he also had responsibility for clinical operations, biostatistics and data management. Dr. Buchanan next served with BioSoteria for 5 years as the head of the medical and safety consulting group, which was subsequently acquired by Dohmen Life Science Services. Dr. Buchanan is currently president of Covilance, LLC, a drug safety consulting service. He is also a co-lead on the Interactive Safety Graphics taskforce, within the American Statistical Association Biopharmaceutical Safety Working Group, that is developing novel, open-source interactive graphical tools to identify and evaluate safety issues during drug development.

Dr. Tarek Hammad, VP & Global Head of Medical Safety for Marketed Products Development, Plasma Driven Therapies, and Medical Device Safety at Takeda Pharmaceuticals, is a renowned expert in drug safety, benefit-risk assessment, and pharmacoepidemiology. With extensive experience at major pharmaceutical companies like Sanofi and Merck, as well as a distinguished 13-year career at the US FDA, he has received numerous awards for his contributions. Dr. Hammad is a sought-after speaker, actively involved in industry initiatives and has held several academic appointments. He has authored over 80 peer-reviewed articles, book chapters, and letters to the editor, offering valuable insights in the field. Learn more at www.DrTarekHammad.com.

Lian Lin, PhD, 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.