ASA Biopharmaceutical Section

Safety Scientific Working Group

ASA-DIA Safety Working Group Quarterly Scientific Webinar - Q3 2023

The Safety Scientific Working Group is sponsored by the Biopharmaceutical (BIOP) section of the American Statistical Association (ASA). 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. This effort is a public-private partnership between the working group which was established in 2021. Drug Information Association (DIA) has been supporting the effort since 2017 as well. Currently co-hosted by Mengchun Li (Merck) and Susan Mayo (FDA), the scientific webinar is a communication forum under its outreach branch (lead by Michelle Zhang (AffaMed)), to ensure efficient communication and exchange between the ASA Biopharm Safety Scientific Working Group and the broader global communities.

If you are interested in learning more about the working group, please contact SafetyWGASA@gmail.com, or visit the webpage at **Safety Scientific Working Group**.

The **2023 Q3 scientific webina**r will be held on **October 2nd (11:00-12:30 EST).** The scientific webinar is free. No registration is required. Please add the meeting info to your calendar.

Abstract: *Recently, CIOMS WG XII Benefit-Risk report was released, outlining the benefit-risk (BR) landscape and promoting the use of a structured BR framework (SBRF) from the beginning and continuously updated and applied throughout the product lifecycle, including key decision-making steps. The report also mentioned the visualization of benefit-risk assessment (BRA) and its importance in the BR process. Members from CIOMS WG XII will provide an overview of this document. Members from BRAP and BRATS will discuss the WG's deliverables and progress (such as BRAP's template that is under development), and BRATS efforts and considerations for an R-Shiny based interactive tool. The discussion will be focused on:*

1) How BRAP and BRATS efforts align with the CIOMS XII's work

2) Potential areas for BRAP and BRATS to consider adjustments/improvements based on CIOMS XII and FDA guidance documents

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Agenda:

11:00- 11:05	**Opening** *Susan Mayo (Senior Mathematical Statistician, US FDA)* *Mengchun Li (Senior Director, Clinical Research, Merck & Co., Inc.)*
11:05-11:35	**CIOMS Working Group (WG) XII Report: Overview and Chapter II-Structured BR approach/framework** *Hong Yang (Senior Advisor for Benefit-Risk, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, US FDA)*
11:35-12:05	**CIOMS Working Group (WG) XII Report: Chapter III-BR methodology considerations** *Leo Plouffe (Global Patient Safety Head, Gilead)*
12:05- 12:15	**Panel Discussion** *Lisa Rodriguez (Deputy Division Director, DBIX, US FDA)* *Mike Colopy (Statistical Safety Scientist, Safety Statistics & Standards Group, UCB)*
12:15-12:25	**Q&A** *All the speakers & panelists*
12:25- 12:30	**Final Conclusion/adjourn** *Susan Mayo (Senior Mathematical Statistician, US FDA)* *Mengchun Li (Senior Director, Clinical Research, Merck & Co., Inc.)*

Speakers	Biography
 **Dr. Hong Yang**	**Dr. Hong Yang** is a senior advisor on Benefit-Risk in the Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, US Food and Drug Administration. Since joined FDA in 2004, she has led many benefit-risk assessments to inform CBER regulatory decisions. She has been active in research and collaboration to develop novel benefit-risk approaches, as well as training and outreaching for implementation of FDA benefit-risk framework. She was a member of FDA Benefit-Risk Guidance Working Group and FDA Benefit-Risk Framework Implementation team. She contributes to CIOMS (COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES) Working Group XII report (CIOMS Working Group XII Benefit-Risk Balance for Medicinal Products). She also actively participates in two American Statistical Association Safety Working Group teams, Benefit-Risk Assessment Planning and Benefit-Risk Assessment Tool Suites. Dr. Yang is also a member of International Society for Pharmacoepidemiology Benefit Risk Assessment, Communication and Evaluation special interest group.

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Dr. Leo Plouffe

Dr. Leo Plouffe brings more than 25 years of industry experience. He was most recently at Bayer for more than 12 years, where he held leadership roles within U.S. Medical Affairs before taking on the role of Global Head of Benefit-Risk Management, Pharmacovigilance. In that role, he worked in collaboration with functions across Bayer to implement a new benefit-risk management process across the portfolio and R&D pipeline. Prior to Bayer, Leo was at Eli Lilly for more than 12 years, holding roles of increasing responsibility in both Clinical Development and Medical Affairs across a broad range of therapeutic areas. He started his medical career as a faculty member at the Medical College of Georgia, where he achieved the position of Professor, Section Chief of Reproductive Endocrinology and Genetics.

Leo earned his medical degree and completed residency training in obstetrics and gynecology at McGill University Medical School. He is dual boarded by the American Board of Obstetrics and Gynecology in Obstetrics and Gynecology and Reproductive Endocrinology. He is also a member of the Royal College of Physicians and Surgeons of Canada, Obstetrics and Gynecology. He has authored more than 70 publications in peer-reviewed journals, served as editor of two medical textbooks and contributed to numerous medical chapters and reviews. Leo has been active throughout his career in driving industry standards and currently serves on the Council for International Organizations of Medical Sciences (CIOMS) and is co-chair for the CIOMS XII – Benefit-Risk writing group.

Leo, along with his wife Eve, who is also an ob-gyn surgeon, and their Beauceron Gaston enjoy spending time outdoors and entertaining their friends visiting from across the United States.

Dr. Lisa Rodriguez

Dr. Lisa R. Rodriguez is the Deputy Division Director of the Division of Biometrics IX, Office of Biostatistics, Center for Drug Evaluation and Research at FDA, supporting hematology products. She received her Ph.D. degree in Statistics from Cornell University.

Prior to joining FDA in 2012, Dr. Rodriguez worked for several years in industry supporting a variety of therapeutic areas, in addition to a research/teaching position at the North Carolina State University Statistics Department and Bioinformatics Research Center. Her work at FDA has covered issues in oncology, hematology, meta-analyses, benefit-risk evaluations for regulatory decision making, stem cell products, evaluation of biomarker and PRO/COA endpoints, survival analyses, biosimilars and adaptive designs. She has also participated in several advisory committee preparations, from both industry and FDA perspectives.

While at FDA, Dr. Rodriguez also completed the Excellence in Government (EIG) Fellows Leadership Program and Strategic Decision and Risk Management Certification from Stanford University. She is currently co-leading the Benefit-Risk Assessment Planning (BRAP) Taskforce within the ASA Biopharmaceutical Section Safety Working Group and is part of several internal FDA scientific working groups.

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Dr. Mike W. Colopy

Mike W. Colopy, MPH, PhD has supported clinical trials and epidemiological studies since 1982. Viewing life as a series of decisions and positive tradeoffs, Mike's vision of benefit-risk assessment is to see it extend beyond treatment-level and patient-level assessments for regulatory decisions to the individual patient level for shared doctor-patient decisions in the clinic. This progression is demonstrated in his UCB team's recent online publication, Planning Benefit-Risk Assessments Using Visualizations, Therapeutic Innovation & Regulatory Science | Home (springer.com).

Zoom Meeting link: SWG Scientific Webinar Q3 2023

ASA Biopharmaceutical Section is inviting you to a scheduled Zoom meeting.
Topic: SWG Q3 23 scientific webinar
Time: Oct 2, 2023 11:00 AM Eastern Time (US and Canada)

Join Zoom Meeting
https://us06web.zoom.us/j/81488221569?pwd=RVZlRHFvc2JCTHpXN3BIZ2VaTThzUT09

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