ASA Biopharmaceutical Section

ASA Safety Working Group Quarterly Scientific Webinar – Q2 2026

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 2026 Q2 scientific webinar, we will discuss challenges and opportunities in transparency, accessibility, and standardization of publicly available clinical trial safety data, with a focus on improving reporting practices to support regulatory decision-making, evidence synthesis, and drug development. The webinar will be held on **June 4, 2026 (11:00 AM – 12:30 PM EST)**. The scientific webinar is free, and no registration is required. Please add the meeting information to your calendar.

Agenda	
11:00 - 11:05	**Opening/Introduction** *Susan Mayo, US Food and Drug Administration* *Ranjeeta Sinvhal, AbbVie*
11:05 - 11: 25	**Guidelines on reporting of adverse effects – why, what, and how?** *Speaker: Yoon K Loke, Medicine & Pharmacology at the University*
11:25 – 11:45	**Publicly Available Clinical Trial Safety Data: A Review and Call for Standardization and Improved Reporting Practices** *Speaker: Barbara Hendrickson, University of Chicago*
11:45 – 12:25	**Panel Discussion & Q&A** *Moderator: Ranjeeta Sinvhal, AbbVie* *Panelists:* *Lian Lin, Scholar Rock*
12:25 – 12:30	**Closing remarks**
Meeting info	**Meeting link:** Click Here **Meeting ID:** 830 5326 4071 **Passcode:** 123456

Abstract:

Complete and transparent reporting of clinical trial safety data, including the assessment methods used, is essential for multiple stakeholders. Regulatory authorities, healthcare providers, and patients need to understand the conclusions and limitations afforded by the clinical trial data when making decisions. Pharmaceutical companies seek to understand the safety data from other relevant products to inform new drug development.

The rapid expansion of systematic reviews and meta-analyses in the 1990s stimulated intense academic efforts towards extraction and synthesis of clinical trial data on adverse effects. However, early researchers encountered considerable challenges in evaluating safety data, particularly with inconsistent and incomplete reporting of adverse effects in journal publications. Since then, various guideline groups have attempted to improve the comprehensiveness and transparency of reporting adverse effects, culminating in the current iteration of CONSORT Harms 2022 - updated guideline for the reporting of harms in randomized trials.

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Recently Work Stream 1/3 of the ASA Safety Working Group published a study regarding the content of public sources of safety data. This study examined the availability of adverse event (AE) information from multiple public sources, with a focus on their utility in contextualizing rates of anticipated events of interest for clinical trial populations. The study found that public data sources often lack consistency and sufficient level of detail which hinders their usefulness. Based on these findings, specific recommendations are made about information to be included in journal publications, regulatory summaries posted at product approval, and ClinicalTrials.gov.

Participants	Bio
 **Dr. Barbara Hendrickson**	Dr. Barbara Hendrickson is on faculty at the University of Chicago and a former Vice President of Pharmacovigilance and Patient Safety at AbbVie. Dr. Hendrickson is a physician with subspecialty training in pediatrics and infectious diseases. She has over 20 years of pharmaceutical industry experience and was a key contributor to multiple product regulatory submissions. She co-leads the Interdisciplinary Safety Evaluation Workstream of the American Statistical Association Biopharma Safety Working Group and participates in PHUSE and PSI work groups.
 **Dr. Yoon K Loke**	Dr. Yoon K Loke is Professor of Medicine & Pharmacology at the University of East Anglia, Norwich, UK. He trained in Clinical Pharmacology and Internal Medicine at the University of Oxford. His main research interest in drug safety and he has been substantially involved in conducting systematic reviews of adverse effects He is a founding member of the Cochrane Adverse Effects Methods Group and has contributed to the CONSORT and PRISMA guidelines on reporting harms in journal publications.
 **Dr. Lian Lin**	Dr. Lin is 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. His recent experience includes pioneering work in tool development, methodology for observational study and safety signal detection. He is an active member of the ASA Safety Working Group and co-leads WS3 on RCT and RWE for safety decision-making.