ASA Biopharmaceutical Section

ASA Safety Working Group Quarterly Scientific Webinar – Q2 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 foster collaboration among academia, industry, and regulatory bodies, integrating expertise from statistics, epidemiology, and clinical science to advance innovation with respect to safety methodology, planning, signal detection and profiling, risk management, and benefit-risk evaluation throughout the drug development lifecycle. Education and tool development are core to our mission to help facilitate informed decision-making and impactful outcomes.

In the 2025 Q2 scientific webinar, we are presenting Emerging Tools to Support DILI Assessment in Clinical Trials with Abnormal Baseline Serum Liver Tests or Pre-existing Liver Diseases on **April 24 (11:00-12:30 EST)**. The scientific webinar is free. No registration is required. Please add the meeting info to your calendar.

Agenda	
11:00 – 11:05	**Opening/Introduction** *James Buchanan, Covilance LLC*
11:05 – 12:00	**Title:** Emerging Tools to Support DILI Assessment in Clinical Trials with Abnormal Baseline Serum Liver Tests or Pre-existing Liver Diseases **Speaker:** *Paul "Skip" H. Hayashi, MD, MPH, FAASLD*
12:00 – 12:25	**Panel Discussion:** *Barbara Hendrickson, University of Chicago* *Cindy McShea, UCB Bioscience*
12:25 – 12:30	**Closing remarks**

Join Zoom Meeting

Meeting ID: 878 7928 7236
Passcode: 123456

Speakers	Bio
 **Paul "Skip" H. Hayashi, MD, MPH, FAASLD**	Dr. Hayashi is the Associate Director of DILI within the Division of Hepatology and Nutrition, FDA. He got his BA in microbiology at UCLA and MD at UC San Diego. After residency and gastroenterology training at UC Davis, he completed a research fellowship at the NIH and a transplant fellowship at the University of Colorado. He received an MPH at Saint Louis University, Missouri. In 2006, he became Medical Director of Liver Transplantation at the University of North Carolina serving in that capacity as associate and then full professor before joining the FDA in 2020. His research and publications have focused on drug-induced liver injury for the last 20 years. He was a Co-Investigator for the NIH Drug-Induced Liver Injury Network and remains Co-Chair of the Causality Committee.

ASA Biopharmaceutical Section

Speakers	Bio
 **Barbara Hendrickson, MD**	**Dr. Barbara Hendrickson** is on faculty at the University of Chicago and a former Vice President of Pharmacovigilance and Patient Safety at AbbVie. She is a physician with subspecialty training in pediatrics and infectious diseases. Dr. Hendrickson has 20 years of pharmaceutical experience and has been involved in multiple product submissions to global health authorities. She has extensive experience with clinical trial safety planning, monitoring and data assessment. She co-leads the Interdisciplinary Safety Evaluation workstream and the Aggregate Safety Assessment Planning task force of the American Statistical Association Biopharm Safety Monitoring Working Group. She also has authored multiple publications related to clinical trial safety.
 **Cindy McShea, MPH**	**Cindy McShea** received a BS in Mathematics from East Carolina University in North Carolina, USA and completed an MPH in Biostatistics from the University of North Carolina at Chapel Hill in North Carolina, USA. Cindy is a senior director of Biostatistics at UCB Biosciences where she leads the Safety Statistics Team within the Biometrics and Quantitative Sciences group. She has over 25 years of experience in the pharmaceutical industry, 20 of which have been spent in statistical and leadership roles within late phase clinical development in neurology and immunology therapeutic areas. She is a contributing member of the Drug Information Association-American Statistical Association Aggregate Safety Assessment Planning Task Force.