ASA Biopharmaceutical Section

ASA Safety Working Group Quarterly Scientific Webinar – Q3 2024

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 2024 Q3 scientific webinar, we are presenting **Addressing Data Challenges in Drug-Induced Liver Injury (DILI)** on **October 24 (11:00-12:00 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** *Susan Mayo (Senior Mathematical Statistician, US FDA)* *Michelle Zhang (Executive Director, Stealth BioTherapeutics)*
11:05 - 11:35	**Data quality issues in clinical development and submissions** *Veronica Pei (Lieutenant Commander, U.S. Public Health Service; Lead Physician, Associate Director for Biomedical Informatics, CDER, US FDA)*
11:35 – 11:45	**Panel Discussion** *Mike Fries (Head, Biostatistics, CSL Behring)* *Jürgen Kübler (Owner, Quantitative Scientific Consultant)* *Xiao Ni (Head of DMD Biostatistics, Sarepta Therapeutics)*
11:45 - 12:00	**Q&A** *All speaker and panelists*
12:00-12:05	**Final Conclusion/Adjourn** *Susan Mayo (Senior Mathematical Statistician, US FDA)* *Michelle Zhang (Executive Director, Stealth BioTherapeutics)*
Zoom Link	*Safety Working Group Quarterly Scientific Webinar – Q3 2024*

Abstract:

Identification of drug-induced liver injury (DILI) is hindered by the lack of a structured, standardized approach to its identification and evaluation. This leads to inefficiencies for both sponsors and regulators. Guidance related to data submission for DILI evaluation can improve the efficiency of regulatory review, for example, by reducing the number of information requests sent by the FDA to industry sponsors. Ultimately, improved strategies for DILI data gathering and submission will also improve the accuracy of DILI risk assessment.

This webinar will delve into a detailed discussion of the challenges associated with reviewing clinical data and propose potential strategies to enhance data quality and improve efficiency. For instance, the ASA Safety Working Group's ASAP Taskforce has suggested a template for ongoing aggregated safety assessment planning. This template includes sections on identifying safety topics of interest, determining the necessary safety data collection to address those topics, outlining methods for data collection, and strategies for analysis. Sponsors can utilize this template as a guide to identify safety topics and develop strategies and plans for safety data collection and analysis.

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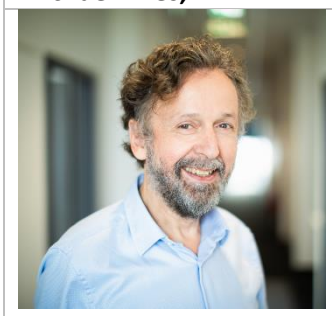
The Interactive Safety Graphics (ISG) Taskforce developed an interactive eDISH tool and an interactive patient profile app to facilitate sponsors to enhance the ability of identifying DILI cases within the framework of ASAP.
By aligning with the suggested template and deploying the interactive tools, employing best practices for proactive planning, data collection and analysis, sponsors can contribute to more effective safety assessment within the clinical research and regulatory context.

Speakers	Bio
 **Veronica Pei, MD**	Dr. Y. Veronica Pei is a commissioned officer in the U.S. Public Health Service currently serving as Lead Physician for the Biomedical Informatics and Regulatory Review Science (BIRRS) team in the Office of New Drugs (OND), FDA. She is board-certified in emergency medicine and clinical informatics. In her current role, Dr. Pei is serves as subject-matter expert on numerous committees and working groups related to data standards, business informatics, and governance and is involved in development, implementation, and support of bioinformatics initiatives within OND, including the Standard Safety Tables and Figures. She is also FDA's topic lead for ICH M11 expert working group on the Structure and Content of Clinical Protocols.
 **Michael Fries, PhD**	Mike is currently the head of Biostatistics at CSL Behring, where he has worked for over 9 and half years. He has nearly 25 years in the industry, having previously worked at GSK and TAP pharmaceuticals. He also spent several years as a visiting Assistant Professor in the School of Computer Science at DePaul University. He is a member of ASA Safety Scientific Working Group, and has a specific Interest in Quantitative Decision Making in drug development and applications of Bayesian Statistics.
 **Jürgen Kübler, PhD**	Co-Chair of Safety Working Group Executive consultant at QSciCon 30+ years of experience in drug development with a focus on drug safety Statistician by training
 **Xiao Ni, PhD**	Xiao Ni is Head of DMD Biostatistics at Sarepta Therapeutics, a biotechnology company based in Cambridge, Massachusetts. In this capacity, he leads 3 biostatistics teams to support 4 Duchenne developmental programs. He also leads a group of 9 Data Scientists at Sarepta to increase efficiency and enable rapid data insights through modern data science tools & mindset. He has been a member of the ISG since 2018 and contributed to ISG tool library such as safetyGraphics, qtexplorer, etc. Xiao is passionate about open-source collaboration.