ASA Biopharmaceutical Section

ASA Safety Working Group Quarterly Scientific Webinar – Q4 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 Q4 scientific webinar, we will discuss new recommendations which inform MedDRA PT groupings to support signal detection and evaluation as well as description of a product's safety profile through labelling on **Nov 6 (11:00-12:30 EST)**. The scientific webinar is free. Please add the meeting info to your calendar.

Agenda	
11:00 - 11:05	**Opening/Introduction**
11:05 - 11:20	**PHUSE Updates – AE Groupings in Safety (AEGiS) Project Team** *Mac Gordon and Peg Fletcher*
11:20-11:35	**Introduction to MedDRA Labeling Grouping (MLG): A Standardized Approach to Grouping Adverse Reactions in Product Safety Labels** *Radhika Rao and Scott Proestel*
11:35-11:50	**How the AEGiS White Paper and MLG Recommendations Impact Aggregate Safety Assessment Planning** *Barbara Hendrickson*
11:50 – 12:15	**Panel Discussion**
12:15 - 12:25	**Q&A** *All speakers and panelists*
12:25-12:30	**Final Conclusion/Adjourn**
Meeting Link	*Safety Working Group Quarterly Scientific Webinar – Q4 2024*

Abstract:

The Medical Dictionary for Regulatory Activities (MedDRA) is a standardized collection of highly granular medical terms which facilitates sharing of medical product information internationally. "Verbatim" adverse event (AE) reports by healthcare providers are coded to "Preferred Terms (PTs)" in MedDRA. Depending on the wording of the "verbatim" report or due to varying presentations of a diagnosis, AEs which represent a similar medical condition may code to different MedDRA PTs.

This webinar discusses new recommendations which inform MedDRA PT groupings to support signal detection and evaluation as well as description of a product's safety profile through labelling.

The AE Groupings in Safety (AEGiS) cross-functional project team within PHUSE's Safety Analytics Working Group has developed a white paper which discusses the selection and use of published MedDRA queries (e.g. Standardized MedDRA Queries [SMQs], FDA Medical Queries [FMQs]) or, if needed, custom queries for clinical trial safety assessments.

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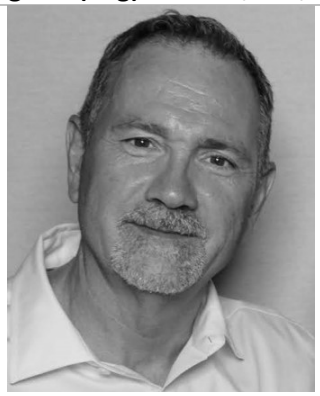
The CIOMS Expert Working Group on MedDRA Labelling Groupings (MLGs) have published consensus recommendations regarding the creation and use of MLGs, in product prescribing information. The MLGs support a more consistent approach for the description and frequency calculation of suspected adverse reactions from clinical trial data.

An Aggregate Safety Assessment Planning (ASAP) process has been proposed by the American Statistical Association (ASA) Interdisciplinary Safety Evaluation scientific working group. The ASAP is a document internal to a clinical trial sponsor which guides product level safety data collection and analyses in clinical development. The AEGiS white paper and CIOMS MLGs put forth important pertinent recommendations that should be considered when creating the ASAP for a product.

Speakers	Bio
 **Margaret (Peg) Fletcher, MD, PhD**	**Margaret (Peg) Fletcher, MD, PhD** is an oncologist and clinical pharmacologist with over 25 years' experience in drug development and safety of oncology, neurology, and metabolic disease products, Dr. Fletcher is an expert in evaluating drug safety data and balancing corporate obligations with patient safety. She has led or supported safety portions of 12+ new or supplemental drug or biologics applications, with FDA approval for 4 new chemical entities and 5 sNDAs. Peg received her MD & PhD (biochemistry) from the University of Chicago and held executive roles in Oncology, Safety & Pharmacovigilance, and Licensing before founding MedAssessment.
 **Mac Gordon, MS**	**Mac Gordon, MS**, received a Masters in Statistics and graduate certificates in Public Health, Pharmacovigilance and Pharmacoepidemiology. He has been involved in pharmacovigilance, signal detection and safety data visualization for most of his career, including membership and leadership in several multi-disciplinary industry working groups. Currently he is a compound statistical lead at Janssen coordinating across 11 indications and several therapeutic areas. His focus has been late development immunology and clinical trial safety for the past 17 years. Mac is involved on many internal teams focused on safety statistics and leads process development initiatives, currently the implementation of the ASAP process.
 **Barbara Hendrickson, MD**	**Barbara Hendrickson, MD** 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 of the American Statistical Association Biopharm Safety Monitoring Working Group. She also has authored multiple publications related to clinical trial safety.

 **Scott Proestel, MD**	**Scott Proestel, MD**, is Vice President of Medical Informatics at Medpace, Inc. He is board certified in Internal Medicine and Clinical Informatics and was an Assistant Professor of Medicine at Georgetown University for three years. Prior to joining Medpace, he worked at the US FDA for 19 years as a medical officer, team leader, and division director in pre-market and post-market safety, where he also conducted research on the use of artificial intelligence to evaluate spontaneous safety reports and queries using large language models. He served at the NIH as a Deputy Director and then Director of the Office for Policy in Clinical Research Operations where he oversaw operations for six global clinical trial networks.
 **Radhika Rao, MD MPH**	**Radhika Rao, MD**, is a Medical Director at AbbVie. With clinical practice experience over 15 years as an Internist and Spinal cord Injury Medicine specialist, Dr. Rao served veterans at Edward Hines, Jr. Veterans Affairs hospital in Chicago. She also was on faculty as an assistant professor of medicine at Loyola Medical Center and participated in medical education at Loyola. Dr. Rao joined Pharmacovigilance at AbbVie Inc. in 2013 contributing to the safety monitoring of products and MedDRA Management Committee training (maintenance of CMQs with MedDRA versioning etc). Dr. Rao delivers lectures in Pharmacovigilance and actively participates in the CIOMS MedDRA Labeling Expert working Group.