

Safety Analytics



Working Group Scope

A cross-disciplinary collaboration working to improve the content and implementation of clinical trial safety analyses for medical research, leading to better data interpretations and increased efficiency in the clinical drug development and review processes.

Current Projects

[AE Groupings in Safety \(AEGiS\)](#)

[Adverse Event Collection Recommendations](#)

[Analyses & Displays for Hepatotoxicity](#)

[Treatment Emergent Definitions Recommendations](#)

[Interactive Analyses and Displays for Laboratory Data](#)

[Safety Analytics Education](#)

Resources

Safety Analytics Education

Patient safety is an important responsibility of sponsors and regulatory authorities throughout the drug development process. To better aid the statisticians, statistical programmers, and data scientists who are engaged with these efforts, the PHUSE Safety Analytics working group has developed an [educational subcluster](#) to provide these quantitative scientists with a deeper understanding of the key concepts in this growing discipline.

If you have any comments or new ideas you want to see on the [Education Page](#), submit them to us at workinggroups@phuse.global.

- [Community Forums](#):
 - [Reimagining a Safety Submission – Vision of Interactive Safety Reviews](#)
 - [Reimagining a Safety Submission – Aggregate Safety Assessment Planning](#)

Estimands in Oncology Safety Task Force

The Pharmaceutical Industry Working Group on Estimands in Oncology in collaboration with PHUSE has started a Safety Task Force on estimands in safety, focusing on oncology. The Task Force will formulate recommendations regarding formulation and use of safety estimands in oncology clinical trials as well as identifying applications of estimands principles to help improve general safety reporting. Recommendations will include trial design, data collection, and analysis issues and ways to integrate clinical, statistical, operations, and data management aspects of study design and execution cooperatively. Key task force activities will include a dive into literature on the subject, formulation of recommendations, development of white papers, and preparation of journal manuscripts and conference presentations. Click [here](#) for Biography.

For more information, please contact Jonathan Siegel at Jonathan.siegel@bayer.com. For information on the Pharmaceutical Industry Working Group on Estimands in Oncology, please visit www.oncoestimand.com or contact Working Group co-chairs, Degtyarev Evgeny at evgeny.degtyarev@novartis.com or Kaspar Rufibach at kaspar.rufibach@roche.com.

Visit the [PHUSE website](#) to search for all Safety Analytics deliverables.



Working Group Lead
Mary Nilsson

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Research Advisor Safety Analytics, Global Statistical Sciences, Eli Lilly. Mary received a MS degree in statistics from Iowa State University in 1989. She has been employed at Eli Lilly since 1989 and is currently a research advisor in the Safety Analytics group within the Statistical Sciences function.

Mary consults with compound teams on safety analysis planning for Phase 2-3 studies and integrated submission documents. Her primary interests include analyses of adverse event data, analyses of laboratory data, statistical analysis plans, and collection of analysis of suicide-related events.



Working Group Lead
Greg Ball

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After graduating from Northwestern University with a bachelor's in economics, Greg served in the Navy for 4 years and taught high school math and physics for 5 years before going back to school to get a master's in applied statistics from Purdue University. Eventually, while working as a statistician, he earned his PhD in biostatistics from the University of Texas Health Science Centre. Gregs current research on blinded safety monitoring procedures emerged from his early work at academic medical centres (MD Anderson and the Methodist Hospital) and CRO's (West and Quintiles), developed into his college dissertation and continues to be developed in collaboration with statistical and clinical scientists from several pharmaceutical companies (Astellas, AbbVie and Merck). Greg established, with Bill Wang, the ASA Biopharm Safety Monitoring Working Group and is pioneering the joint DIA-ASA Interdisciplinary Safety Evaluation (DAISE) scientific Working Group, to advocate for aggregate safety assessments and cross-disciplinary scientific engagement.



Working Group Lead
Scott Proestel

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Scott Proestel, MD, is Acting Assoc Biomedical Informatics and Regulatory Team at the US Food and Drug Administration for Drug Evaluation and Research. He completed his internal medicine training at Hopkins Hospital and obtained his Columbia University Vagelos College of Physicians and Surgeons. He has previously worked as a medical officer and team leader at the FDA, supervising pre-market reviews of applications, overseeing HIV clinical trials, Office Director at the US National Institutes of Health and worked as an FDA Division D post-market safety surveillance in the FDA's Center for Biologics Evaluation and Research.

Scott's most recent informatics research includes the use of artificial intelligence to evaluate safety reports submitted to the FDA's Adverse Event Reporting System and Vaccine Adverse Event Reporting System.