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.

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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.

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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.

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Scott Proestel, MD, is Acting Assc
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Team at the US Food and Drug A
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completed his internal medicine tr
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Scott's most recent informatics res
use of artificial intelligence to eval
safety reports submitted to the FD
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Reporting System.