Safety Analytics

Working Group Scope
TA cross-disciplinary collaboration working to improve the content and implantation of clinical trial safety analysis 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
Analyses & Displays for Laboratory Data
Listings for Clinical Study Reports
Treatment Emergent Definitions Recommendations

Mary Nilsson: Working Group Lead

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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.

Greg Ball: Working Group Lead

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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.