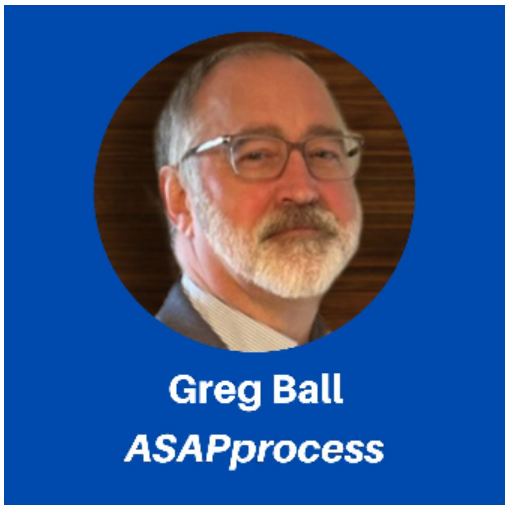
Reimagining a Safety Submission – Aggregate Safety Assessment Planning

Reimagining a Safety Submission – Aggregate Safety Assessment Planning
During this Community Forum, presenters introduced two new FDA premarket safety analytics documents and discussed how past and current efforts from cross-industry Working Groups can be leveraged to prepare the ecosystem for operationalising them. This Community Forum took place over Zoom on 16 February 2023. Carry on the conversation by posting your comments on the Disqus forum below!

Catch up here!
This Community Forum took place 16 February 2023. Catch up by viewing the recording. Got a question for the presenters? Submit it to the online Disqus forum posted below!

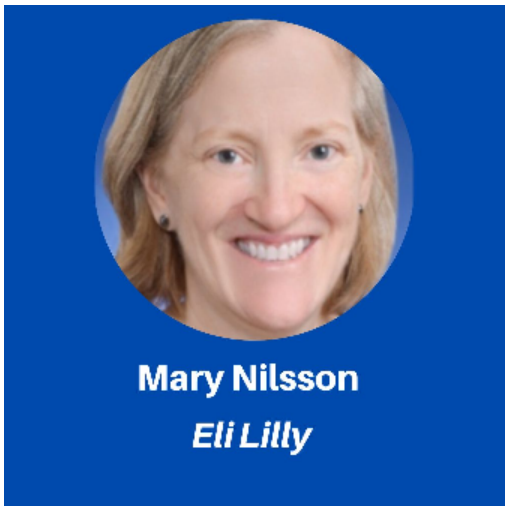

Topic	Presenter(s)
Welcome	Greg Ball & Mary Nilsson, *Safety Analytics Working Group Leads*
A New Framework for Interdisciplinary Safety Evaluation – A Learning and Decision-Making Approach	Greg Ball, *ASAPprocess*
DIA-ASA Interdisciplinary Safety Evaluation (DAISE) Working Group: The Aggregate Safety Assessment Planning (ASAP) project team	Barbara Hendrickson, *University of Chicago*
Resources Informing Content for Safety-related Analysis Plans	Mary Nilsson, *Eli Lilly*
PHUSE AE Groupings in Safety (AEGiS) project team	Robert (Mac) Gordon, *Janssen Research & Development*
Discussion	

Presenter	Bio



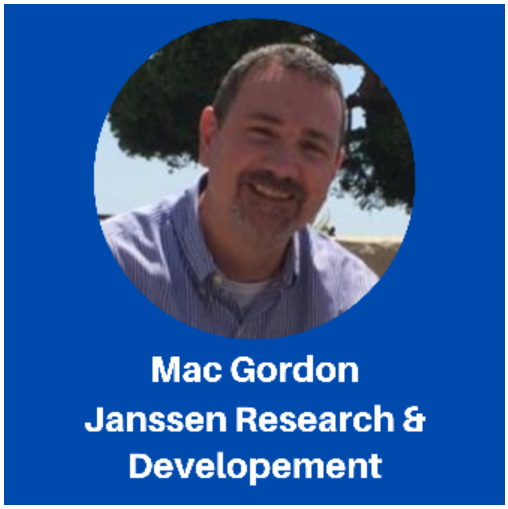
Greg Ball, *ASAPprocess*

Greg Ball served in the Navy and taught High School maths and physics before earning his master's in statistics from Purdue and his PhD in Biostatistics from the University of Texas. His research on blinded safety monitoring procedures is being developed in collaboration with statistical and clinical scientists at several pharmaceutical companies (including AbbVie and Merck). With Mary Nilsson, Greg co-leads the PHUSE Safety Analytics Working Group. Greg established, with Bill Wang, the ASA Biopharm Safety Monitoring working group and has been pioneering the joint DIA-ASA Interdisciplinary Safety Evaluation (DAISE) scientific working group, to advocate for aggregate safety assessments and cross-disciplinary scientific engagement.



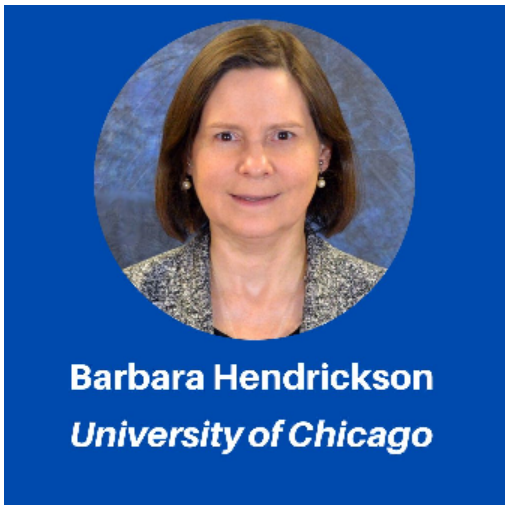
Mary Nilsson, *Eli Lilly*

Mary Nilsson is Executive Director-Statistics, Safety Analytics at Eli Lilly. Mary received her master's degree in statistics from Iowa State University in 1989 and has been employed at Eli Lilly since then. She is currently a researcher in the Safety Analytics group. Mary consults with molecule teams on safety analysis planning for Phase II to III studies and integrated submission documents. Her primary interests include analyses of adverse event data, analyses of laboratory data, statistical analysis plans, and collection and analysis of suicide-related events. Additionally, she co-leads the PHUSE Safety Analytics Working Group, creating cross-functional education and cross-industry recommendations for standard safety analyses and displays.



Mac Gordon, *Janssen Research & Development*

Mac Gordon has a master's in statistics and graduate certificates in public health, pharmacovigilance and pharmacoepidemiology and has been with Janssen for 15 years, and in industry for 20 years. He has been involved with lupus research since joining the organisation, with focus areas in late-development immunology and clinical trial safety. Mac has been heavily involved in pharmacovigilance, signal detection and safety data visualisation for most of his career, including membership in several multi-disciplinary industry/regulatory working groups. Prior to joining Janssen, Mac developed a safety surveillance and signal detection team at Cephalon. He is currently the Clinical Team Statistical Lead across 11 indications and several therapeutic areas. Outside of clinical research, Mac is involved in many internal teams focused on safety statistics and process development initiatives and continues to represent the organisation in external safety Working Groups.



Barbara Hendrickson, *University of Chicago*

Dr Barbara Hendrickson is a former Vice President of Pharmacovigilance and Patient Safety at AbbVie. She is currently on faculty at the University of Chicago. Dr Hendrickson is a physician with subspecialty training in paediatrics and infectious diseases and has 19 years of pharmaceutical industry experience. She has been involved in multiple new product and additional indication submissions and has participated in several clinical trial safety initiatives and the implementation of internal data monitoring committees. In addition, Dr Hendrickson co-leads the DIA-ASA Aggregate Safety Assessment Planning Working Group.

Resources
PHUSE Community Forum Welcome
A New Framework for Interdisciplinary Safety Evaluation – A Learning and Decision-Making Approach
Resources Informing Content for Safety-related Analysis Plans
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