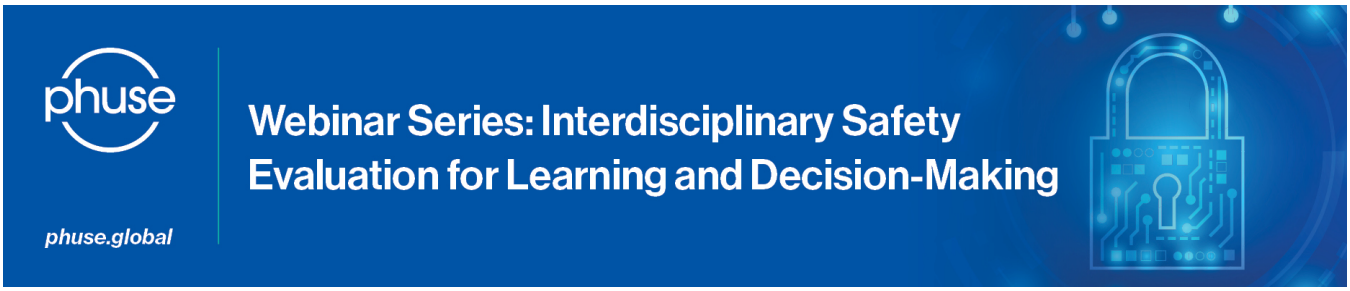
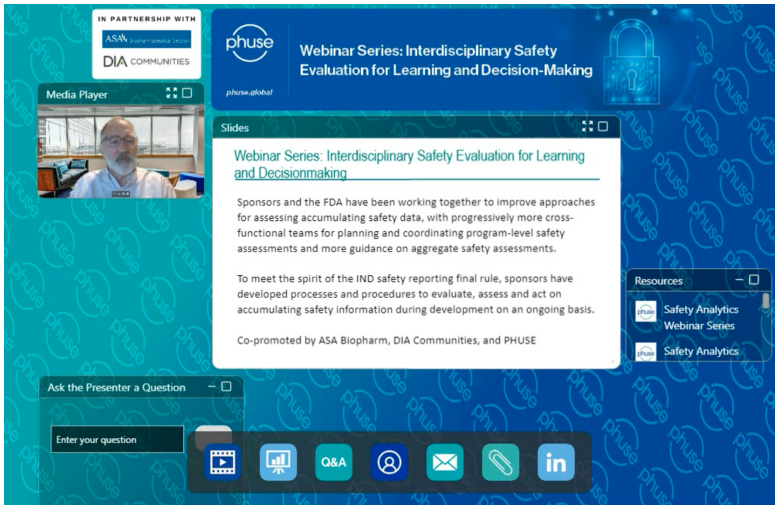
Overall Safety Assessment – Standard Safety Tables and Figures



Catch up here!

This Webinar took place 13 July 2023. Catch up by viewing the recording or reading the slides.



Webinar Series: Interdisciplinary Safety Evaluation for Learning and Decisionmaking

Sponsors and the FDA have been working together to improve approaches for assessing accumulating safety data, with progressively more cross-functional teams for planning and coordinating program-level safety assessments and more guidance on aggregate safety assessments.

To meet the spirit of the IND safety reporting final rule, sponsors have developed processes and procedures to evaluate, assess and act on accumulating safety information during development on an ongoing basis.

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Webinar 2: Overall Safety Assessment – Standard Safety Tables and Figures

Summary:

Industry standards for data collection and storage have evolved over time: Clinical Data Acquisition Standards Harmonization (CDASH), observed data (SDTM) and analysis datasets (ADaM). However, efforts to align on a systematic approach to analyse safety data from randomised clinical trials are relatively new. Currently, many individual companies and regulatory review divisions are developing their own standard tables and figures, and these standards tend to have a lot of variation. While some might be warranted, the extent of the variation is leading to inefficiencies in programming, tool development, interpretation, number of information requests from regulators to sponsors and less efficient ways to share learning and introduce new methods. During this webinar, presenters will share a summary of efforts related to developing standard safety tables and figures.

This is the second of five webinars related to interdisciplinary safety evaluation, with an overall goal to improve the content and implementation of safety analysis for medical research so we have better data interpretations, better decision-making and increased efficiency in the clinical drug development and review processes.

Click here to view the other webinars in the series.

Presenter	Bio
	**Dr James Buchanan, *Covilance*** Dr James Buchanan is an independent drug safety consultant. He graduated from the University of California, San Francisco with a PharmD degree in clinical pharmacy. He worked in the area of clinical toxicology at the Bay Area Regional Poison Control Center at San Francisco General Hospital before entering the pharmaceutical industry. Dr Buchanan began his industry career at Genentech, where he worked for nine years in the areas of medical information and drug safety in the clinical development department. He subsequently moved to Gilead Sciences to establish a drug safety department. After leaving Gilead Sciences, he started the drug safety department at Tularik, where he acted as Chief Safety Officer until the company was acquired five years later by Amgen. Following the merger with Amgen, he moved to Nuvelo to establish a drug safety department and act as Chief Safety Officer, where he also had responsibility for clinical operations, biostatistics and data management. Dr Buchanan next served with BioSoteria for five years as the head of the medical and safety consulting group, which was subsequently acquired by Dohmen Life Science Services. Dr Buchanan is currently president of Covilance, a drug safety consulting service. He is also a co-lead of the American Statistical Association Biopharmaceutical Safety Working Group and is a co-lead on the Interactive Safety Graphics taskforce that is developing novel, open-source interactive graphical tools to identify and evaluate safety issues during drug development.
	**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. 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.

Dr Veronica Pei, *FDA*

Dr Veronica Pei is a board-certified emergency physician and a commissioned officer in the U.S. Public Health Service, currently serving as an Associate Director for Biomedical Informatics (ADBMI) in the Office of New Drugs (OND) at the FDA. In this role, Dr Pei is involved in development, implementation and support of bioinformatics initiatives as well as data standards within the OND. She is the current FDA topic lead for the ICH M11 expert working group on the Structure and Content of Clinical Protocols. She also serves as lead for the FDA Standard Safety Tables and Figures Integrated Guide. Prior to joining the FDA, she was a practising emergency physician, with interests in medical education and global emergency medical system development. After completing her BSc in Biological Sciences at the University of Toronto and her MD at McMaster University, Dr Pei received a master of education in health professional education from the University of Toronto. She subsequently completed residency training in emergency medicine at the Hospital of the University of Pennsylvania and fellowship training in international emergency medicine and received a master of public health in international health policy and programs at The George Washington University.

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