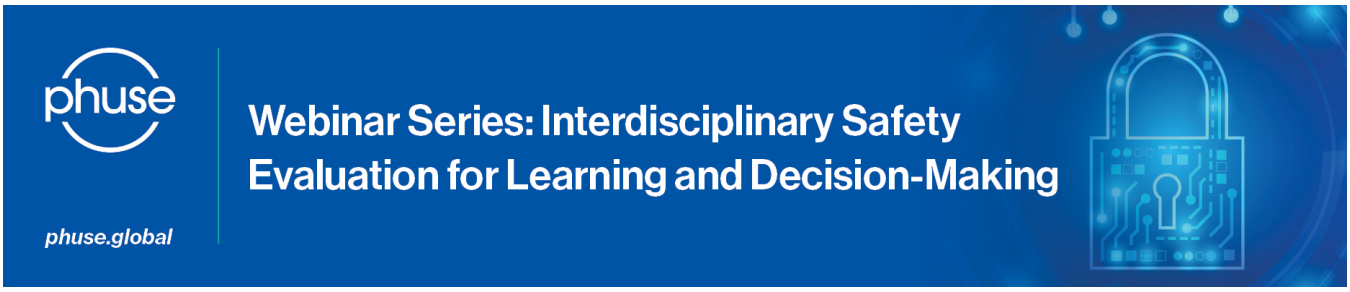
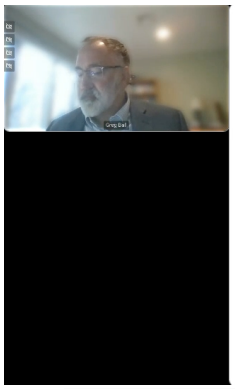
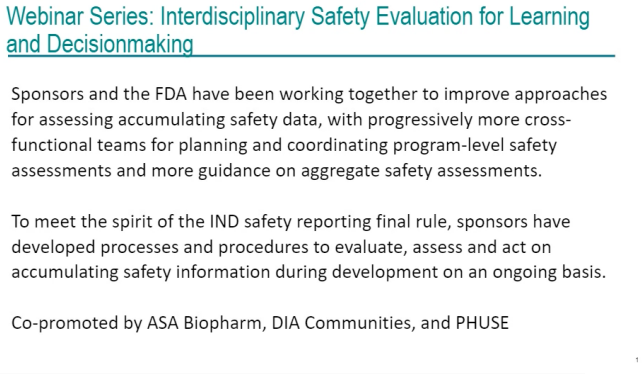
Interdisciplinary Safety Evaluation for Learning and Decision-Making: Education for Executives



Catch up Here!

This Webinar took place 16 November. 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.

Co-promoted by ASA Biopharm, DIA Communities, and PHUSE

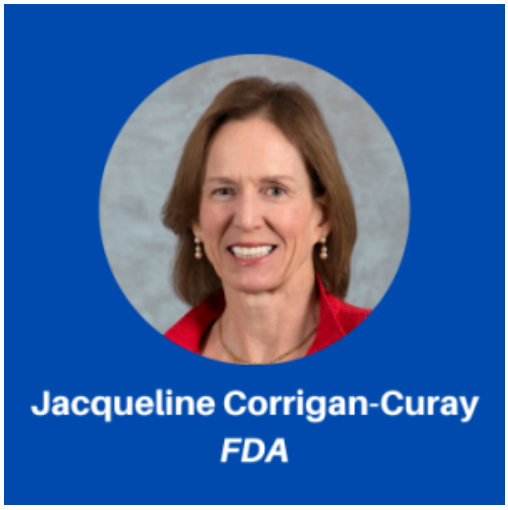
Webinar 5: Interdisciplinary Safety Evaluation for Learning and Decision-Making: Education for Executives

Summary:

This was the final webinar in a series of five webinars related to interdisciplinary safety evaluation, with an overall goal to improve the content and implementation of safety analysis for medical research, leading to better data interpretations, better decision-making and increased efficiency in the clinical drug development and review processes.

Jacqueline Corrigan-Curay (FDA) set the stage with a regulatory perspective on the IND Safety Reporting Final Rule and the new FDA Medical Queries and Standard Safety Tables and Figures. Sheila Mahoney (LifeSciHub) provided a business case to senior leaders for devoting additional resources to achieve a more proactive approach to clinical safety assessment. Greg Ball (ASAP Process) explained how meeting the spirit of the final rule requires a culture change in how we do programme-level safety assessments throughout the clinical development life cycle. And Barbara Hendrickson (University of Chicago) advocated for an aggregate safety assessment planning process to scientifically evaluate accumulating programme-level safety information, support IND reporting decisions, operationalise FDA Medical Queries (FMQs) and Standard Safety Tables and Figures, and leverage interactive safety graphics for safety data assessment and communication.

Jacqueline Corrigan-Curay closed out the webinar and the series highlighting how FDA–industry partnerships have strengthened aggregate safety assessments to improve identification and characterisation of risks for a medicinal product on a programme level. Approaching safety differently as a result of the IND Safety Reporting Final Rule can positively impact the bottom line and mitigate PR risk.

Presenter	Bio
	**Greg Ball, *ASAP Process Consulting*** 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.
	**Jacqueline Corrigan-Curay, *FDA*** Jacqueline Corrigan-Curay, J.D., M.D., is the Principal Deputy Center Director in the FDA's Center for Drug Evaluation and Research (CDER), where she provides executive leadership on strategic initiatives that advance CDER's mission to deliver safe, effective and high-quality medications to the American public. Prior to taking on this role, Dr. Corrigan-Curay was the director of CDER's Office of Medical Policy leading the development, coordination and implementation of medical policy programmes and strategic initiatives, including on real-world evidence, use of technology in drug development and prescription drug promotion. Before joining the FDA, she served as senior medical officer with the Immediate Office of the Director, National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served as Director of the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH. Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA.

Dr Barbara Hendrickson, *University of Chicago*

Dr Barbara Hendrickson is on faculty at the University of Chicago and a former Vice President of Pharmacovigilance and Patient Safety at AbbVie. She is a physician with subspecialty training in paediatrics and infectious diseases and has 19 years of pharmaceutical industry experience. In addition to involvement in multiple new product and supplementary indication submissions, she has led several company safety initiatives. One initiative was a pilot project for ongoing blinded clinical trials, which implemented a process using pre-designated assessment entities to support IND safety reporting decisions based on aggregate safety data. In addition, Dr Hendrickson co-leads the DIA-ASA Aggregate Safety Assessment Planning (ASAP) Working Group, which has published suggested best practices for the ASAP process.

Sheila Mahoney-Jewels, *MBA*
Sheila Mahoney-Jewels has spent almost 25 years at the intersection of sponsor operations and the life sciences R&D technology and professional services vendor ecosystem. Her industry-recognised thought leadership efforts include Co-Founder and Co-Chair of the Drug Information Association (DIA)'s Regulatory Information Management Working Group, Regulatory Team Lead for the Framework for Paper Destruction v2.0, Co-Founder, Co-Chair of the DIA Annual 2023 Professional Development Track, and the Center for the Transformation of Work – in alignment with the Laboratory for Innovation Science at Harvard. Sheila was elected to PharmaVoice's Top 100 Most Inspiring 2019 Entrepreneur Award. Sheila holds a BA in Environmental Studies (major: Evolutionary Biology; minor: Public Policy) from Smith College and an MBA from Columbia University.

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