

## The Fearless Statistician: Psychological Safety in Drug Development

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### Anna Wiksten

#### Please provide a brief biography for the Presenting author(s)

Anna Wiksten, PhD, has worked for the past 15 years on various drug development projects as a statistician and statistical programmer. Beyond her current role as a statistician at BMS, she is the chairperson for SSL (Statisticians in the Finnish Pharmaceutical Industry) and an EFSPi council member. She has broad experience in indirect treatment comparisons, regulatory submissions, and estimands. She is passionate about understanding the big picture in drug development and finding ways for statisticians to improve drug development processes through technical and people leadership skills

### Dirk Klingbiel

#### Please provide a brief biography for the Presenting author(s)

Dr. Dirk Klingbiel is an experienced Biostatistician and Drug Developer with a proven track record in clinical research. He has extensive experience in statistical consultation, protocol development, and data analysis, and is committed to advancing drug development through rigorous scientific methodologies and strategic insights. Dr. Klingbiel has held leadership roles where he has led and guided teams, mentored new hires, and built the external reputation of organizations through academic and industry collaborations. His interest in leadership topics is evident in his ability to effectively collaborate with diverse stakeholders and influence peers. Dr. Klingbiel also has a long-standing interest in psychological safety in the workplace.

### Kristina Weber

#### Please provide a brief biography for the Presenting author(s)

Kristina is a Principal Statistical Scientist at Roche and has been primarily working on late phase Neuroscience studies since 2018. Prior to joining Roche Kristina worked as a statistician for the Medical School Hannover, where she was involved in clinical trials across different indications and development phases. Kristina holds a PhD on pediatric extrapolation from the Medical School Hannover and has studied Mathematics.

### Single topic, multi-speaker session, Workshop or Single presentation submission

A single topic, multi-speaker session/workshop

### Single topic session or workshop abstracts

Talk #1 - Introduction to psychological safety and its relevance to statisticians working in the pharmaceutical Industry

Every pharmaceutical company wants to innovate and excel, and statisticians have much to offer that may help their companies get there. But somewhere along the way there are missed opportunities—times when things are going in the wrong direction, and we are either not speaking up or not having the influence needed to course correct. Amy Edmondson and Timothy Clark have studied and written a lot about psychological safety—defined here as the perception or belief that one will not be punished or humiliated for speaking up with ideas, questions, concerns, or mistakes. They find that team and corporate performances

are highly related to the degree of psychological safety that their members experience—this trumps skill, experience, and seniority. In this introduction to the session, we will define key concepts and their relevance to our field.

## Talk #2 - Organizational Approaches to Psychological Safety: Building Inclusive and High-Performing Statistical Teams

Psychological safety is a structured construct that can transform how statisticians contribute within their organizations. This talk will focus on the four key stages of psychological safety and how they may manifest in statistical teams and the broader overarching organization.

The first stage is inclusion safety which ensures that team members feel they belong, regardless of cultural differences, personalities or the hectic nature of daily business. It is the starting point of helping ensure that all voices are heard. Second is learner safety which requires an environment where it is safe to admit lack of experience or expertise paired with enthusiastic curiosity, and a bit of humility. This is crucial as the complexity of drug development often requires new learnings and acknowledgements of uncertainty.

Third is contributor safety where people feel comfortable to share their own ideas or expertise without fear of humiliation or being ignored. A vital step for statisticians who rely on being comfortable bringing new ideas and accepting input from cross-functional team members. And finally there is challenger safety where people feel empowered and capable of highlighting alternative strategies, methods, or mistakes. This stage is essential for preventing mistakes and ensuring robust, data-driven decision-making.

This talk will showcase the journey of one organization that has adopted these principles, demonstrating how psychological safety at each stage enhances team dynamics and ultimately improves drug development.

## Talk #3 - Quantifying the costs of a lack of psychological safety - A case series

Imagine you are part of the team working on a new medicine with blockbuster potential. The study reads out positive, and you and the team are busily preparing all of the documentation, data, and reports for submission to health authorities. Suddenly, during the final review you find a mistake in the primary endpoint. What are the costs of pointing this out? What are the costs of not pointing this out? Will your career survive this dilemma? This talk will walk through the concepts of psychological safety in hypothetical examples from drug development. We will quantify the impact of psychological safety both from financial and employee well being perspective.

Panel Discussion: speakers + Justine Rochon, Lucy Rowell