



International Alliance for
Biological Standardization

11th Annual Statistics Workshop: Big Tent Statistics - Conveying the Importance of Statistical Contributions

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Virtual Meeting

Statistical Empowerment through Collaboration with Method SMEs

Updates to regulatory guidance on assay validations present a vital opportunity for statisticians to collaborate effectively with method subject matter experts (SMEs) in establishing robust acceptance criteria. These new guidelines stress the need for statistical intervals to align with predefined criteria, a challenge that goes beyond the straightforward assessments of averages and standard deviations typically performed by method SMEs.

This presentation will explore the collaborative synergy between statisticians and method SMEs in developing meaningful statistical interval criteria to evaluate accuracy and precision in assay validations. We will discuss leveraging historical data to inform these criteria, the impact of sample sizes on interval widths, and a methodology for transitioning from standard point estimates to interval-based criteria. Through case studies, we will illustrate how statisticians can engage proactively with method SMEs, shaping discussions and decision-making processes from the outset.

Our ultimate goal is to equip method SMEs with the necessary knowledge and tools to independently generate and refine their criteria for future assay validations. By fostering early collaboration and mutual understanding, we can ensure the adoption of scientifically sound and regulatory-compliant practices, thereby enhancing the reliability and credibility of assay validation outcomes. This approach not only elevates the role of statisticians but also positions them as strategic partners in the validation process.

