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# 9th Annual IABS Statistics Workshop
# Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

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**Title: Joint Assessment of Accuracy and Precision in Analytic Transfer"**

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**Introduction** – US Pharmacopeia (USP) <1224> requires a documented process to qualify new laboratories to use analytical procedures originating from another lab. As statistical methods for transfers are not prescribed, a comparative testing approach was developed.

**Challenges** – Though USP suggests setting criteria on relative standard deviation for variability, which requires no prior data to set, it becomes unstable as means approach zero. Even with historical data informing criteria, challenges such as unsuitable distribution, outliers, and failure to meet criteria should be considered. Alignment in criteria should also be considered, as methods of comparable risk should be transferred with comparable rigor.

**Proposed Approach** – A comparative testing approach is proposed using standardized data to jointly assess bias and variability between labs. Confidence intervals are applied to quantify worst case plausible differences and determine their acceptability. Justification for setting criteria may include scientific rationale, impact to specification, historical performance, and risk-based quality decisions.

**Conclusions** – The proposed approach allows a desirable tradeoff between bias and variability while preventing the mutual extremes allowed by independent criteria. Statistical power is improved by leveraging historical data from the originating lab in both criteria setting and the transfer itself, and the approach remains functional when historical data is absent. Finally, uniformity of scale allows for risk-based alignment between methods and standardization of criteria.