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TITLE: Optimal Design of Experiments for Powerful Equivalence Testing

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ABSTRACT: Robustness studies in biopharmaceutical and biological manufacturing are routinely conducted to demonstrate that, under normal operational variability, process responses remain equivalent to those at nominal operating conditions. While equivalence is the primary inferential objective, commonly used experimental designs are typically optimized for estimation or prediction and can therefore provide inadequate power for equivalence testing. We propose a new semi-Bayesian optimal design criterion, termed powerful equivalence (PE) optimality, for studies intended for equivalence assessment via the Two One-Sided Tests procedure. PE-optimality maximizes the probability of correctly concluding equivalence across the experimental region. This criterion provides a statistical framework for both design selection and run size determination. We show that PE-optimal designs consistently attain higher regional equivalence power than conventional optimal designs for a fixed run size. We illustrate the methodology with a robustness design for a vaccine adjuvant manufacturing process.

BRIEF SPEAKER BIO: Ying Chen holds an M.Sc. in Statistics and Data Science and is a doctoral researcher at the Department of Biosystems, KU Leuven, Belgium. Her main research area is optimal design of experiments for process robustness studies.