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Optimal Experimental Designs for Process Robustness Studies

Friday, 30 May 2025 11:15 (20 minutes)

In process robustness studies, experimenters are interested in comparing the responses at different locations within the normal operating ranges of the process parameters to the response at the target operating condition. Small differences in the responses imply that the manufacturing process is not affected by the expected fluctuations in the process parameters, indicating its robustness. In this presentation, we propose an optimal design criterion, named the generalized integrated variance for differences (GID) criterion, to set up experiments for robustness studies. GID-optimal designs have broad applications, particularly in pharmaceutical product development and manufacturing. We show that GID-optimal designs have better predictive performances than other commonly used designs for robustness studies, especially when the target operating condition is not located at the center of the experimental region. In some situations that we encountered, the alternative designs typically used are roughly only 50% as efficient as GID-optimal designs. We will demonstrate the advantages of tailor-made GID-optimal designs through an application to a manufacturing process robustness study of the Rotarix liquid vaccine.

Type of presentation

Contributed Talk

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