Title: Optimal Experimental Designs for Process Robustness Studies

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Biography:

- Ying Chen is a doctoral researcher at the Department of Biosystems, KU Leuven, Belgium.
- Bernard G. Francq is the Associate Director of CMC Statistical Sciences, GSK, Rixensart, Belgium.
- Peter Goos is a full professor at the Faculty of Bio-Science Engineering of KU Leuven, and at the Faculty of Business and Economics of the University of Antwerp, Belgium.

Summary of the presentation: 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 will introduce a new optimal design criterion, named the generalized integrated variance for differences (GI_D) criterion, to set up experiments for robustness studies. GI_D-optimal designs have broad applications, particularly in pharmaceutical product development and manufacturing. We will show that GI_D-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, the alternative designs typically used are roughly only 50% as efficient as GI_D-optimal designs. We will also demonstrate the advantages of tailor-made GI_D-optimal designs through an application to a manufacturing process robustness study of the Rotarix liquid vaccine.