Einladung zum Biometrischen Kolloquium

Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

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MULTI-OBJECTIVE DOSE-FINDING

14. Februar 2017 um 10:00 Uhr

Jugendstilhörsaal, Rektoratsgebäude (BT88)
Medizinische Universität Wien, Spitalgasse 23, 1090 Wien

Gastgeber: Franz König

Abstract:

The main purpose of dose-escalation trials is to identify the dose(s) that is/are safe and efficacious for further investigations in later studies. In this talk we introduce dose-escalation designs that incorporate both dose-limiting events (DLEs) and efficacy into the procedure. A flexible non-parametric model is used for modelling the continuous efficacy responses while a logistic model is used for the binary DLTs. Escalation decisions are based on the combination of the probabilities of DLTs and expected efficacy through a gain function. Based on this setup, we then introduce two types of Bayesian adaptive dose-escalation strategies. The first type (”single objective”’) of procedures aims to identify and recommend a single dose, either the maximum tolerated dose (MTD), the highest dose that is considered as safe; or the optimal dose, a safe dose which gives optimum benefit-risk. The second type (”dual objective”’) aims to jointly estimate both the maximum tolerated dose (MTD) and the optimal dose accurately. The recommended dose(s) obtained under these dose-escalation procedures provide information about the safety and efficacy profile of the novel drug to facilitate later studies. We evaluate different strategies via simulations based on an example constructed from a real trial on Type II Diabetes patients and the use of stopping rules is assessed.