Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz
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Einladung zum

BIOMETRISCHEN KOLLOQUIUM

am **Freitag, 20.Mai 2016** um **9:00 Uhr**

im Seminarraum (Ebene 3, Raum 88.03.513) des
Zentrums für Medizinische Statistik, Informatik und Intelligente Systeme (CeMSIIS)
der Medizinischen Universität Wien, Spitalgasse 23, 1090 Wien
(Plan siehe http://www.muw.ac.at/cemsiis/allgemeines/anschrift/)

Vortragende:

LISA HAMPSON

Lancaster University, UK

OPTIMAL GROUP SEQUENTIAL TESTS FOR DELAYED RESPONSES WITH NON-BINDING FUTILITY BOUNDARIES

UND

EKKEHARD GLIMM

Novartis Pharma, Basel, Switzerland

SOME UPDATES ON WEIGHTED PARAMETRIC TESTS

Wir freuen uns auf zahlreichen Besuch.

Franz König
Präsident

Stephan Lehr
Sekretär

Abstracts

Optimal group sequential tests for delayed responses with non-binding futility boundaries

Lisa V Hampson, Chris Jennison

Group sequential tests propose monitoring data as they accumulate from a clinical trial rather than waiting until the end of a study to make a final decision. One-sided group sequential tests are usually designed assuming that recommendations to stop a trial early, for efficacy or lack of benefit, will always be adhered to. Unplanned deviations from a binding futility rule will cause inflation of the type I error rate. However, a sponsor may wish to have the flexibility to continue a trial even after a futility boundary has been crossed in order to gather additional data on safety or key secondary endpoints. In this presentation we formulate group sequential designs for delayed responses with non-binding futility rules. Delayed responses are common in practice since clinical interest often lies in testing the long-term effects of a new treatment on patients' health. We seek tests which control the type II error rate when early stopping recommendations are always followed, and control the type I error rate when futility boundaries are always disregarded. We use dynamic programming to find optimal versions of designs satisfying these frequentist error rate constraints as solutions to Bayes decision problems. Properties of optimal rules are used as a benchmark to understand the relative efficiencies of competing designs specifying futility boundaries on the basis of predictive or conditional power, for example.

Some updates on weighted parametric tests

Ekkehard Glimm, Dong Xi, Willi Maurer, Frank Bretz
Novartis Pharma, Basel, Switzerland

We describe a general framework for weighted parametric multiple test procedures based on the closure principle. We utilize general weighting strategies that can reflect complex study objectives and include many procedures in the literature as special cases. The proposed weighted parametric tests can be represented using rejection rules with adjusted significance levels or by using adjusted p-values. It is instructive to explore this connection, because it the equivalence of these two different representations is not always immediately obvious.
We also show that a subclass of exact α-level parametric tests (which uses proportional upscaling of the local levels in a closed test procedure) satisfy the consonance property. When only subsets of test statistics are correlated, a new procedure is proposed to fully utilize the parametric assumptions within each subset. We illustrate the proposed weighted parametric tests using a clinical trial example.