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

BIOMETRISCHEN KOLLOQUIUM

am **Dienstag, 17. März 2015** um **14:00 Uhr** (s.t.)

In der Informatik-Bibliothek (Ebene 3, Raum 88.03.806) 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/)

Vortragender:

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FLEXIBLE ALPHA ALLOCATION STRATEGIES FOR CONFIRMATORY ADAPTIVE ENRICHMENT CLINICAL TRIALS WITH A PRE-SPECIFIED SUBGROUP

Wir freuen uns auf zahlreichen Besuch.

Franz König
Präsident

Stephan Lehr
Sekretär

FLEXIBLE ALPHA ALLOCATION STRATEGIES FOR CONFIRMATORY ADAPTIVE ENRICHMENT CLINICAL TRIALS WITH A PRE-SPECIFIED SUBGROUP

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Abstract:

In adaptive enrichment designs, it is often the case that trial sponsors have some prior belief that there will be a large treatment effect in a pre-specified subgroup compared to the overall population. Hence, it is natural to consider allocating more significant level to the pre-specified subgroup than to the overall population, such that the likelihood of establishing efficacy claim in at least one of the two populations is increased.

In this talk, we extend and apply several statistical approaches to allow for such unequal alpha splitting strategies between overall population and a pre-specified subgroup in confirmatory adaptive enrichment designs. First, we extend the Spiessens and Debois test to allow for unequal alpha splitting and use it in connection with the closed combination test as well as a degenerate closed combination test. Second, we apply an adaptive graph-based multiple test procedure which is based on a sum of conditional error rates. Third, we use an idea of marginally combining stagewise p-values and extend the Spiessens and Debois test to adaptive settings. Finally, we perform a simulation study to compare the operating characteristics of the statistical approaches.