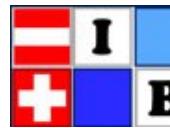## MEDIZINISCHE UNIVERSITÄT WIEN

Zentrum für Medizinische Statistik, Informatik und
Intelligente Systeme (CeMSIIS)

Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

Einladung zum Biometrischen Kolloquium

Gastgeber:

Zentrum für Medizinische Statistik, Informatik und Intelligente Systeme (CeMSIIS)
Medizinische Universität Wien

MARIUS THOMAS (NOVARTIS, CH)

EXPLORATORY SUBGROUP ANALYSES IN CLINICAL TRIALS

20. April 2017 um 15:00 Uhr

Informatik-Bibliothek (Ebene3, Raum 88.03.806)CeMSIIS, Spitalgasse 23, 1090 Wien
http://www.muw.ac.at/cemsiis/allgemeines/anschrift/

Abstract:

Identifying subgroups, which respond differently to a treatment, both in terms ofefficacy and safety, is an important part of drug development. A well-known challengein exploratory subgroup analyses is the small sample size in the considered subgroups,which is usually too low to allow for definite comparisons. In early phase trials thisproblem is further exaggerated, because limited or no clinical prior information on thedrug and plausible subgroups is available. While a variety of different subgroupidentification methods have been developed for the situation of trials that studyan experimental treatment and control, much less work has been done in the situation when patients were randomized to different dose groups.

In this talk we give an overview over the main challenges of the setting and review some recent tools for exploratory subgroup analyses. We then present an extension of the model-based recursive partitioning approach by Seiboldet. al (2016) to subgroup analyses for trials with several dose groups. We show that the method can be used to identify subgroups of patients with different dose-response curves and improves estimation of treatment effects and minimum effective doses, when heterogeneity among patients is present.

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