Einladung zum Biometrischen Kolloquium

Gastgeber: Martin Posch (Medizinische Universität Wien)

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DATA COMBINATION IN SEAMLESS PHASE II/III CLINICAL TRIAL DESIGNS

7. September 2017 um 16:00 Uhr

Informatik-Bibliothek (Ebene3, Raum 88.03.806) des Zentrums für Medizinische Statistik, Informatik und Intelligente Systeme (CeMSIIS) Medizinische Universität Wien, Spitalgasse 23, 1090 Wien
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Abstract:

In a seamless Phase II/III clinical trial, one of several treatments or doses is selected in Phase II for further study in Phase III. The final decision rule for declaring the selected treatment superior to control must protect the family-wise type I error rate for comparisons of all treatments against the control. When a combination rule is applied to P-values from data in the two phases, we find that overall power does not always increase beyond that obtained by simply ignoring the Phase II data! This raises the question of how one should combine information to maximise power while protecting family-wise type I error.

We present a formulation of the problem which is amenable to analysis by decision theory. Hence, we derive optimal data combination rules for particular objectives --- and find some surprising results. We are able to identify decision rules with robust efficiency across a variety of scenarios. We quantify the effective information obtained from the Phase II data and we show how to go about optimising the division of resources between Phase II and Phase III.