

Kolloquium „Statistische Methoden in der empirischen Forschung“

Wann: 22. Oktober 2013, 17:00 – 18:30 Uhr

Wo: Landwirtschaftlich-Gärtnerische Fakultät der HU, Hörsaal 2, 2. Etage,
Invalidenstr. 42, 10115 Berlin

Dr. Björn Bornkamp (Novartis, Basel)

Dose-Finding Studies – Design, Analysis and Implementation using the DoseFinding R package

The go/no go decision and the selection of dose(s) for Phase III confirmatory trials are among the most difficult decisions in drug development. Well-planned and executed Phase II dose-finding trials hence play a major role in this process, as they generate the key information for making these decisions.

In this talk I will first provide background information on the aims and objectives of dose-finding trials and will then introduce the MCP-Mod methodology in some detail. The methodology is a hybrid statistical technique for dose-finding studies that combines the advantages of both multiple comparisons and dose-response modeling techniques. Latest developments for the MCP-Mod methodology will be reviewed (see Pinheiro et al 2013) and sample size calculations will also be considered. The presented method will be illustrated on a real example using DoseFinding R package, which is freely available from the CRAN servers.

References:

Pinheiro et al. (2013) Model-based dose finding under model uncertainty using general parametric models, available under <http://arxiv.org/abs/1305.0889>