

## **Kolloquium „Statistische Methoden in der empirischen Forschung“**

Wann: 21. Januar 2014, 17:00 – 18:30 Uhr

Wo: Landwirtschaftlich-Gärtnerische Fakultät der HU, Hörsaal 2, 2. Etage,  
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### **Dose finding studies with an active control**

In dose finding studies often several doses of a new drug are compared to an already available standard treatment as an active control instead of a comparison with a placebo group. This situation can be modeled in terms of a mixture of two regression models, one for the new drug and the other for the active control. Although it is a common approach in drug development the underlying statistical design problem has rarely been considered in the literature so far.

We give a careful introduction to optimal design theory in the context of active controlled dose finding studies. Under the assumption of normally distributed errors, we present a method of determining optimal designs for estimating the smallest dose achieving the same effect as the active control.

We discuss the question of parameter misspecification and present some possible solutions by considering robust design strategies such as Bayes- and Minimax-optimal designs. For some of the frequently used models, for instance the EMAX-model, some optimal designs are presented.

We finish the talk by discussing the situation when the underlying distribution is not necessarily normal but follows a certain structure.

### *References*

Dette H., Kiss C., Benda N. and Bretz F. (2011). Optimal designs for dose finding studies with an active control. To appear in: Journal of the Royal Statistical Society, Ser. B.