

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

Wann: 24. November 2015, 17:00 – 18:30 Uhr

Wo: Robert Koch-Institut | Nordufer 20 | 13353 Berlin (Wedding),  
S41, S42, U9 Westhafen | U9, Bus 142 Amrumer Str

**Tim Friede (Institut für Medizinische Statistik, Universitätsmedizin Göttingen)**

### **Welche Patienten profitieren am meisten von einer Therapie? Methoden zur Exploration und Konfirmation von Subgruppen**

The identification of subgroups of patients responding particularly well to a treatment has become of increased interest in a move to personalized or stratified medicine. We start by reviewing methods for exploration of subgroups within a single trial (Ondra et al, 2015) with a particular focus on a modification of the Adaptive Refinement by Directed Peeling algorithm by LeBlanc et al (2005). Then we extend these ideas to the setting of several trials using a meta-analytic framework highlighting the importance to model between-trial heterogeneity (Friede et al, 2015). Finally, we consider how subgroup identification and confirmation can be integrated in clinical development plans and discuss the role of adaptive enrichment designs (Friede et al, 2012; Stallard et al, 2014).

Friede T, Parsons N, Stallard N (2012) A conditional error function approach for subgroup selection in adaptive clinical trials. *Statistics in Medicine* 31: 4309-4320.

Friede T, Röver C, Wandel S, Neuenschwander B (2015) Meta-analysis of few small studies in rare diseases. (Submitted)

LeBlanc M, Moon J, Crowley J (2015) Adaptive risk group refinement. *Biometrics* 61: 370-378.

Ondra T, Dmitrienko A, Friede T, Graf A, Miller F, Stallard N, Posch M (2015) Methods for identification and confirmation of targeted subgroups in clinical trials: A systematic review. *Journal of Biopharmaceutical Statistics* (in press).

Stallard N, Homburg T, Parsons N, Friede T (2014) Adaptive designs for confirmatory clinical trials with subgroup selection. *Journal of Biopharmaceutical Statistics* 24: 168-187.