

# Department Seminars

## Target Dose Estimation Under Model Uncertainty: the MCP-Mod Approach

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### Abstract:

Identifying the *right* dose is one of the most important and difficult goals in drug development, having a critical impact on the likelihood of a compound being brought to, and staying in, the market. Decisions derived from dose-response studies can be divided into two main components: establishing that the treatment has some effect on the clinical endpoint, the *proof-of-concept* (PoC) step, and selecting a dose, or doses, estimated to be efficacious and safe for the confirmatory phase, the *dose-finding* step. This talk will present, discuss and illustrate a methodology to test PoC and estimate target doses based on a combination of multiple comparison procedures (MCP) and modeling techniques, the so-called MCP-Mod method (Bretz, Pinheiro, and Branson, 2005). The approach allows for model uncertainty at the PoC step, by using a set of candidate dose-response models which are tested using MCP techniques based on model contrasts. The best of the statistically significant models, if any, is used to estimate target doses in the dose-finding step.

Joint work with Frank Bretz, Novartis Pharma AG.

### Reference:

Bretz, F., Pinheiro, J.C., and Branson, M. (2005) Combining multiple comparisons and modeling techniques in dose-response studies. *Biometrics*, 61(3), 738-748.

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**\*note location change**

**12:00-1:00 p.m.**