

*Symposium Program on Dose Selection for Cancer Treatments: May 12, 2017*

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**Title:** *Collaboration of pharmacometrics and statistics: concentration-response MCPMod*

**Abstract:**

Finding the dose with good benefit-to-risk ratio and selecting the dose(s) for phase III are key tasks in clinical drug development. Characterizing the dose-response relationship is important in this process. However, the same dose can lead to a different drug exposure in patients due to inter-individual differences (e.g., weight, gender, co-medication). Thus, characterizing the exposure-response relationship is as important as characterizing the dose-response relationship. Assuming “exposure drives response”, it may enable clinical trial simulation for objectively predicting untested scenarios, e.g. for special population, for untested dose or dose regimen, for different study duration. MCPMod has been developed under dose response framework and we extended to exposure-response framework. The gain for exposure-response analysis over dose response may depend on the variability of clearance and shape of the curve on observed dose range.