TITLE: Simulation-based optimization of adaptive designs using a generalized version of assurance

AUTHORS: Pantelis Vlachos*, Valeria Mazzanti, Boaz Adler - *Cytel*

presenting author

ABSTRACT:
The power of cloud computing is utilized to create a tool that collects information from different parts of the clinical development team (clinical, operations, commercial etc) and with the statistician at the driver seat seeks and proposes designs that optimize a clinical study with respect to sample size, cost, duration and power. The optimization is performed using a generalized assurance measure that takes into account all trial possible scenarios with respect to treatment effect, control response, enrollment, dropouts etc. Furthermore, this tool can be used to communicate and update information to the trial team in real time, considering (possibly) changing target objectives. Case studies of actual adaptive trials will be given.

PRESENTING AUTHOR BIO:
Pantelis Vlachos is VP of Customer success in Cytel. He designs and implements clinical development programs and clinical trials, performs statistical analysis, and provides critical statistical input to support regulatory compliance. Pantelis has broad clinical research experience spanning early through late-stage clinical development and drug safety assessment in both large-scale pharmaceutical as well as academic settings. Prior to joining Cytel in 2013, Pantelis was a Principal Biostatistician at Merck Serono in Geneva, as well as a Professor of Statistics at Carnegie Mellon University for 12 years. He is a co-founder and former Managing Editor of Bayesian Analysis journal. He has also served on the editorial boards of various other journals, and online statistical data and software archives. Pantelis has contributed to the development of clinical development plans and provided statistical input to submission documents for regulatory authorities. His research interests lie in adaptive designs, mainly from a Bayesian perspective, as well as hierarchical model testing and checking. He has applied his research in studies ranging from Phase I clinical pharmacology and dose escalation, Phase II dose finding, to Phase III studies in oncology, autoimmune disease, vaccines, and other. Pantelis contributes to software development and provides trainings for Cytel's software products in Europe.