

**Blinded Effect Size Evaluations in Clinical Trials using
Gaussian Process Models**

Marc Sobel, Ph.D.

Fox School of Business and Management
Temple University

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3:30-4:30pm, New PI 6th Floor Multipurpose Room (6602)
Light refreshments provided

Abstract

Clinical trials are a major and costly undertaking for researchers and their planning involves careful selection of the primary and secondary endpoints. Failure to consider important secondary endpoints can limit the conclusions of clinical trials. The 2010 draft FDA guidance on adaptive designs discusses possible study design modifications such as selection and/or order of secondary endpoints. The purpose of this presentation is to assess the feasibility of estimating the magnitude of treatment effects on various secondary endpoints in ongoing trials without breaking the treatment blind using Gaussian Process Methodology. Our primary objective is to estimate and compare the signal-to-noise ratios (i.e. effect size) of endpoint using available data points. Gaussian Process Methodology is an effective way of estimating and comparing effect sizes; it does this by properly accounting for inherent relationships between study visits and endpoints.

Biographical Note

PhD (Statistics), University of California at Berkeley, 1983 (under Erich Lehmann)
Tenured at Temple University, Philadelphia, PA in 1994. I worked part-time at Fox Chase Cancer Center (2000-2001), Dept of Bioinformatics, Courant Institute (2005-2006), and Dept of Biology, Drexel University (2012-2013). Formerly, I worked in many areas involving statistical applications of Machine Learning and Robotics. My current interests include: Gaussian Processes, Sequential MCMC (state space models) and Medical Trials.

¹ The PI Biostatistics Seminar Series is held on Tuesdays at New York State Psychiatric Institute. If you are interested in receiving regular announcements for our seminars in the future, or if you need further information, please contact Jina James (jamesji@nyspi.columbia.edu, (212) 543-5589).