



ANNOUNCES A  
COLLOQUIUM

## Dr. Joseph F. Heyse

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will speak on

# Application of False Discovery Rate Methods in Clinical Trials

**Time: 3:00 – 4:00 PM**

**Date: Friday, October 5, 2007**

**Place: Tuttleman Learning Center 401B**

### Abstract

Almost all multiple comparison and multiple endpoint procedures applied in clinical trials are designed to control the Family Wise Error Rate (FWER) at a prespecified level (e.g.,  $\alpha = 0.05$ ). Benjamini and Hochberg (1995) argued that in certain settings, requiring strict control of the FWER is often too conservative. They suggested controlling the False Discovery Rate (FDR), defined as the expected proportion of true hypotheses that are incorrectly rejected. This presentation discusses the potential application of FDR methods in clinical trial settings. When one or more of the hypotheses being tested uses a discrete data endpoint then it is possible to further increase the power of both FWER and FDR controlling procedures. Methods proposed by Tarone (1990) and Gilbert (2005) have increased power by using the discreteness in the data to reduce the effective number of endpoints considered for the multiplicity adjustment. A modified fully discrete FDR sequential procedure is introduced that uses the exact conditional distribution of potential outcomes. The potential gains in power are estimated using simulation. Application of FDR in the setting of clinical safety data analysis is reviewed and other potential uses of the proposed method are discussed.

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