

The  
University of Michigan  
Department of Biostatistics

Presents

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Vancouver, British Columbia

**Neutralizing Antibodies and the Efficacy of Interferon**

Several large multi-center clinical trials have established that Type I interferons favorably influence clinical and magnetic resonance imaging outcomes in relapsing-remitting multiple sclerosis (MS). However, some patients develop neutralizing antibodies (NABs) to these treatments, reflecting an immune system response. The clinical significance of these NABs has been unclear as titers vary widely and elevated NAB titers often diminish to undetectable levels in individual patients. The question of whether NABs impact on the efficacy of these treatments is directly related to the question of how the treatment of MS patients should be managed. It has also become part of the marketing strategy of pharmaceutical companies with different Type I interferons approved for the treatment of MS: hundreds of millions of dollars per year are at stake.

In this presentation, I will describe our involvement with this issue. I will outline the simple cross-sectional analyses which initially raised the concern, and the longitudinal analysis approaches we have taken to try to resolve this issue using data from several completed MS clinical trials.

A fascinating part of our involvement has been persuading the neurological community of the need for a more sophisticated analysis of clinical trial data than is customary in the field to fully address this issue.

**Thursday, October 22, 2009**

**3:30 p.m. – M1152, SPH II**

Coffee and Cookies will be served for seminar guests at  
3:00 p.m. in SPH II, Room M4034