



**October 1**  
**Ivan S. F. Chan**  
**Merck Research Laboratories**

***Assessing Efficacy and Correlates of Protection  
in Vaccine Studies***

*Vaccines are typically developed for disease prevention in healthy subjects. The unique characteristics of vaccine development pose special challenges in designing vaccine efficacy trials. In addition, immune responses are measured to identify potential markers that correlate with efficacy. In this talk, we will discuss the statistical issues involved in design and analysis of vaccine efficacy trials and in assessing correlates of protection. We will illustrate some potential difficulties in applying classical methods (such as Prentice's criteria) for validating surrogate endpoints. Then, we will present some approaches in evaluating correlates of protection, including the concept of protective level and the use of statistical models to examine the relationship between efficacy and the whole distribution of immune responses. Real vaccine examples will be used to illustrate the methods.*