

## Statistical Issues and Challenges in Evaluating New Vaccines

Ivan S.F. Chan, William W.B. Wang, and Joseph F. Heyse  
*Merck Research Laboratories North Wales, Pennsylvania, USA*

Vaccines are biological products that work primarily by introducing antigen or attenuated live virus into the body to trigger an immune response specific for the protection of a targeted disease. Unlike drugs, vaccines are typically developed for prevention of disease in healthy or uninfected subjects and are usually administered in a single series (and with a booster in some cases). Because of their biological nature, typically vaccines also have more variability in manufacturing and are less stable than drugs. In addition, safety is an important consideration for vaccines since they will potentially be administered to millions of healthy individuals. These unique characteristics pose some special challenges in designing vaccine trials and, depending on the targeted disease, often call for very large studies. In this presentation, we will highlight some of key statistical challenges in trial design and analysis. Illustrations will be given using two recent examples from the herpes zoster vaccine (Oxman et al. 2005, NEJM, 352, 2271-2284) and the rotavirus vaccine (Vesikari et al. 2006, NEJM, 354(1): 23-33).

[ Ivan S.F. Chan, Clinical Biostatistics UG 1CD-38 Merck Research Laboratories P.O. Box 1000 North Wales, PA 19454, USA; ivan\_chan@merck.com]