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A new class of distribution-free models in analysis of adverse events in drug safety

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In the area of pharmaceutical drug safety, one of the primary goals in analysis of adverse events (AEs) is to detect any signal of a difference between the treatment and control groups. Traditionally, crude incidence rate, chi-square test or Fisher's exact test, and Miettinen and Nurminen are the useful methods in analysis of single AE data depending on what level of importance it belongs to, such as Tier 1, Tier 2, or Tier 3, which were defined by Merck. Actually, the occurrence of AEs is very complicated. Simple measurement of AE data without enough information including duration effect, severity effect, or recurrent event, the estimation and inference could be biased. Moreover, multiple AEs within the same system organ class (SOC) are usually correlated with each other. So analysis of single AE over simplifies comparison among treatment arms in drug safety. In this presentation, we would like to propose a new class of distribution-free approaches to address the effects of duration, severity, and recurrence of AE data by using a new measurement within certain specified class. The good asymptotic properties and robustness for the proposed models have been shown in this study. The numerical simulation studies and a case study example are provided for illustrations.

Biography

Richard Entsuah is a Fellow of the American Statistical Association. He completed his PhD from University of Michigan. He was an Assistant Professor of Biometry at University of Illinois in Chicago. He joined Wyeth Research from 1988 to 2007 and left as an Assistant Vice President of Global Biostatistics and Programming. He joined Merck Research Labs as Executive Director of Late Development Statistics and is the Research Group 4 Head for Neuroscience and Respiratory Immunology.

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