Title: “Bioequivalence Testing and Drug Interchangeability”

Speaker: Prof Shein-Chung Chow
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Host: Dr. Tan Say Beng
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Abstract:

When an innovative drug product is going off patient, pharmaceutical companies may file an abbreviated new drug application (ANDA) for generic approval. In 1984, the United States Food and Drug Administration (FDA) was authorized to approve generic drug products under the Drug Price Competition and Patent Term Restoration Act. For approval of generic drug products, the FDA requires that evidence of average bioequivalence in drug absorption be provided through the conduct of bioequivalence studies. As indicated in 21CFR320.24, bioequivalence may be established by in vivo (e.g., pharmacokinetic, pharmacodynamic, or clinical) and in vitro studies or with suitable justification by in vitro studies alone. In this presentation, an overview of statistical considerations including study design, criteria, and statistical methods for assessment of bioequivalence will be provided. In addition to average bioequivalence, the concept of population bioequivalence and individual bioequivalence for addressing drug interchangeability (in terms of drug prescribability and drug switchability) will also be discussed. For in vitro bioequivalence testing, an overview regarding profile analysis and non-profile analysis as recommended by the US FDA will be provided. Recent development and future research topics will also be discussed.

Biography:

Shein-Chung Chow, Ph.D. is currently a Professor at the Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina. Prior to that, Dr. Chow also held various management positions in the pharmaceutical industry and at National Health Research Institutes of Taiwan. Dr. Chow is the author or co-author of more than 200 methodology papers and 19 books. Dr. Chow received a B.S. in mathematics from National Taiwan University, Taiwan, and a Ph.D. in statistics from the University of Wisconsin, Madison, Wisconsin.

All are welcome to attend. No registration is required. Light refreshments will be served beginning at 11:45 outside the auditorium.