統計科學研究所
INSTITUTE OF STATISTICAL SCIENCE

SEMINAR STATAS

Postdoc Seminar

Title：Statistical Considerations in New Drug Review Incorporating Bridging Issues

Speaker：Dr. Mey Wang (王 玫 博士)
(Center for Drug Evaluation, Taiwan)

Time：14:00 ~15:00 , Wednesday, May 3, 2023

Place：Auditorium, B1F, Institute of Statistical Science, AS

Abstract

For a medicine to register in a new country, manufacturers are generally required to provide substantial evidence to support the efficacy in the claimed indication in accordance with local regulatory standards. Substantial evidence is usually interpreted as statistically significant results with family-wise type I error rate controlled at two sided 5% from at least two adequately designed phase III confirmatory trials. Or, in special situations, a single pivotal phase III confirmatory trial with statistical evidence considerably stronger than $p < 0.05$.

Recently, geographic variations of efficacy and safety of a medicine has attracted much attention from sponsors as well as regulatory authorities. Taiwan formally announced the requirement of bridging study evaluation (BSE) on January 1, 2004. The Bridging Study Evaluation is to assess whether the efficacy and safety data from the foreign clinical trial can be extrapolated to the patient population in Taiwan (or East-Asian), and to determine whether the recommended dosage is appropriate for the patients in Taiwan.

In this talk, I will briefly introduce the statistical considerations in reviewing a New Drug Application (NDA). Additionally, I will discuss the statistical methodologies that are used to address bridging issues. Two case examples will be presented as a demonstration.

※ Tea reception starts at 15：00.

※ Lecture in Mandarin. Online live streaming through Cisco Webex will be available.