



國立高雄大學統計學研究所

Institute of Statistics, National University of Kaohsiung

演講公告

The Use of Two-Sided Tolerance Interval Testing with Considering the Variability of Batches in the Assessment of Biosimilarity

講者 | 姜 杰教授 (淡江大學數學系)

時間 | 2024年6月5日(星期三)下午3:30-4:30

地點 | 統計所多媒體教室(理學院 320室)

茶會 | 下午3:00 於統計所辦公室(理學院 325室)

摘要

In recent years, with the expiration of several patents for innovative drug, the production of corresponding biosimilar products has become increasingly prevalent. However, there remains a lack of clarity regarding the statistical criteria for assessing the similarity between an innovative biologic and its biosimilar counterpart. Additionally, it is known that the between-batches variability plays a crucial role for the response of a biosimilar product, however, the involvement in the statistical analysis is seldom discussed in the literatures. In this study, we assume that the therapeutic response can be explained by a nested random effect model with the between-batches variability. A two-sided tolerance interval-based hypothesis test is constructed and the statistical properties are investigated by simulation studies with various parameter components. Finally, we use a real example to demonstrate the proposed approach.

Key Words: biosimilarity, two-sided tolerance interval, between-batches variability.

近期演講內容: <https://statsite.nuk.edu.tw/>

高大交通資訊: <https://statsite.nuk.edu.tw/p/412-1037-5044.php?Lang=zh-tw>



(高大統計所)

敬請公告

歡迎參加