

# 安全性に関わる臨床評価の統計的側面

椿 広計  
統計数理研究所

## Statistical aspects of safety-related clinical assessment

Hiroe Tsubaki  
The Institute of Statistical Mathematics

### Abstract

The structure of the null hypothesis differs between safety and efficacy evaluations of new drugs when there are multiple endpoints. Therefore, for the safety hypothesis, the author shows that no adjustment for multiplicity is needed even in the confirmatory testing inference. However, for the safety hypothesis, given the situation where no power-based sample size design is usually used and the probability of producer risk is close to 1. Therefore, a professional interpretation of the test results for the safety hypothesis or revalidation experiments shall be required to decrease the producer risk. In this study, we will also review studies around the journal of clinical evaluation that have examined this type of inference.

### Key words

controller, quality assurance, interaction, heredity principle, multiplicity

*Rinsho Hyoka (Clinical Evaluation)*. 2022 ; 49 (3) : 435-41.