# RESTRICTED RANDOMIZATION-BASED INFERENCE IN RANDOMIZED CONTROLLED TRIALS

T. Hasegawa[1], T. Tango[2], M. Nishikawa[2]

[1]*Shionogi & Co.,Ltd., Osaka, Japan*
[2]*National Institute of Public Health, Saitama, Japan*

Email: *takahiro.hasegawa@shionogi.co.jp*

The selection of a trial design is an important issue in the planning of randomized controlled trials (RCT). One of the most important considerations in trial design is the method of treatment allocation and appropriate analysis plan corresponding to the design. The most common basis of a statistical test is the concept of *population model*, where it is assumed that the sample of subjects is representative of the reference population and that the subject responses are independently and identically distributed. In spite of the lack of a formal sampling in RCT, a population model is then invoked as the basis for data analysis, as though a formal sampling basis existed. Therefore, it is useful to analyze based on the *randomization model*, where it is assumed that the set of observed subject responses is fixed and the treatment assignments is random. In this presentation, we conducted Monte Carlo simulations to evaluate the performance of statistical inference under the invoked population model and the randomization model. Allocation was conducted using five types of allocation methods: complete randomization, random allocation rule, permuted block design, stratified randomization and minimization. When stratified randomization or minimization was used, randomization-based inference provided higher power than invoked population-based without adjustment analysis and slightly lower power than invoked population-based with adjustment analysis.