KEYNOTE SPEAKER

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Topic:

Randomization techniques – theory and practice

Abstract:

The ICH E9 statistical principles for clinical trial guideline states that "the most important design techniques for avoiding bias in clinical trials are blinding and randomization". Thus, using adequate randomization techniques is an important prerequisite in conducting a clinical trial. Over the years various restricted randomization techniques such as permuted block design, biased coin design, urn design or big stick design have been proposed as well as covariate-adaptive and response-adaptive randomization. In this talk, I will discuss the performance of different restricted randomization techniques regarding their treatment balance behavior and allocation randomness. However, it is not only important to have different techniques available but also to have suitable software to allow use of these techniques in practice. I will present a web-based randomization tool for multi-centre clinical studies ("Randomizer" – www.randomizer.at) which was developed by the Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz, Austria. This tool facilitates efficient management of the randomization process including allocation concealment, stratification, audit trails etc. and can also be used for simulation of different randomization designs.