

# 試験統計家の継続的な育成

## — 試験統計家もどきに関連した事件 —

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### Continuing education of clinical trial statisticians: An incident after a sham trial involving a hypertensive drug

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#### Abstract

News features of the valsartan investigator-initiated trial issue reported on the alleged manipulation of data, resulting in that a clinical trial statistician to be publicly blamed in the media for the incident. This kind of public shaming has not occurred in many previous cases of clinical trial-related scandals. Concerning this issue, the Ministry of Health, Labour and Welfare organized “The Discussion Committee about the Clinical Trial of an Antihypertensive Drug” and released an interim draft report which summarized the results of hearings of persons involved in the large-scale clinical trial of valsartan, including the hearing of the biostatistician who conducted the statistical analysis of this trial.

Based on the above-mentioned interim report, the author discussed in this paper the social responsibility of a clinical trial statistician, showing the actions that a real professional trial statistician should have taken in each process of the conduct of the valsartan trial. Additionally, in discussing this large-scale clinical trial, the author demonstrated that plausible sample size setting is possible based on invalid scientific hypothesis setting, which causes crucial bias in analysis that can mar the research results. The conduct and result of a clinical trial which sauntered into such trap of bias could cause substantial negative repercussions not only to the persons involved but to many other people of goodwill.

The author is concerned that this kind of issue may result in the social blame being cast upon clinical trial statisticians in general. It is for this reason that the author, using the valsartan incident as an example, has demonstrated the essence of continuing education of clinical trial statisticians as an important requirement in their career development.

#### Key words

valsartan investigator-initiated trial (IIT) issue, trial statistician, trap of bias, BioS, Declaration of Helsinki

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