

# わが国における医薬品の 市販後臨床試験のあり方を考える： ディオバン（一般名バルサルタン）論文 不正問題から学ぶ教訓と提言

中野 重行

大分大学医学部創薬育薬医療コミュニケーション講座

## Future clinical trials of post-marketing drugs in Japan: Lessons to learn from the Diovan (valsartan) scandal and proposal for a solution

Shigeyuki Nakano

Department of Pharmaceutical Medicine and Communication, Oita University Faculty of Medicine

### Abstract

Lessons to learn from the recent Diovan<sup>®</sup> (valsartan) scandal in Japan were reviewed and a proposal for a solution was presented. The importance of the experimenter effect such as the investigator's expectancy effect was pointed out. Future clinical trials of post-marketing drugs in Japan were discussed. Mandating the preservation of source material to ensure the reliability of clinical trial data is critically important. It is desirable to establish a better framework for clinical trials of post-marketing drugs to improve the quality of medical care.

### Key words

Diovan<sup>®</sup>, valsartan, expectancy effect, clinical trials, post-marketing drug

*Rinsho Hyoka (Clinical Evaluation)* 2014 ; 41 : 699-714.