Clinical trial rigging: again!

In 2013, several publications of trials assessing valsartan were retracted by the journals concerned, because the clinical data had been falsified (a)(1,2).

Overly favourable results... The results of a randomised comparative trial published in 2009 appeared to show that valsartan was highly effective in preventing angina and stroke, while results from previous trials showed that it only had a small effect (3,4).

In early 2013, this article was retracted by the European Heart Journal (published by the European Society of Cardiology), on account of “critical problems”, as were other articles by the same Japanese author (1).

...but they had been tampered with. Following an investigation, the Japanese university that employed the author, who subsequently resigned, revealed that the raw data had been falsified to exaggerate the drug’s benefits in preventing angina and stroke (3). The investigation also revealed that one of the persons involved in the trial was working for Novartis, the company which markets valsartan, although this affiliation was not disclosed in the published article (3).

The investigating committee repeated the statistical analyses, excluding patient data identified as having been falsified; the amended results showed that valsartan did not prevent angina or stroke (3).

Systemic problem. Following this initial scandal, The Lancet retracted an article on another trial of valsartan conducted in Japan, which again had not disclosed the involvement of a Novartis employee (2).

These scandals highlight many flaws in the current clinical research system, such as major, but undisclosed, conflicts of interest; academic authors deprived of access to the raw data; insufficient verification of scientific publications; low-key and inexplicit retractions of articles; and long delays before fraud is discovered.

Clinical research is almost exclusively funded by the pharmaceutical industry and, given the interests at stake, there is a risk of serious distortion of the facts.

In practice. Prescrire assessed valsartan before these articles were published, and its conclusions remain valid. These scandals serve as a reminder that clinical trial results are not an inviolable truth. There is always a possibility that these results will be called into question.

Selected references from Prescrire’s literature search.