Good clinical practice—a question of balance

We refer to the article in your journal 'Good Clinical Practice: a question of balance' [1]. An article written by us both [2] and a book edited by one of us [3] were cited to justify the line 'Recent articles about GCP present the clinical investigator as somebody who will deliberately or carelessly try to do things wrong . . .'. Neither of our texts suggest this. Our article in your journal actually described the rules and regulations of GCP in the USA, the UK and the EC, which we were not involved with drafting. Just a few lines illustrate our own opinion:

'The EC guidelines aim to share responsibilities between investigator, sponsor and authority in harmony, rather than within a legalistic framework. Correctly implemented they increase the input of investigators, and establish clearly their role as key figures in the investigational programme.'

As this shows, we agree with Wallnöfer and Cohen's premises concerning the balance between clinical and bureaucratic requirements.

Nor, it seems, has the book [3] been read before being misrepresented. It describes the detailed GCP requirements, but goes out of its way to explain how an investigator can organise to avoid the tedium of the checking processes and concentrate upon clinical issues and the protection of the patient.

We also note that the FDA's Compliance Audit Programs are cited as American GCP guidelines. This is another misrepresentation. They are manuals used to guide Food & Drug Administration Auditors when they inspect the sites at which clinical investigations have been conducted. These audits are indeed targeted at uncovering fraud and inaccuracy and as such can seem

somewhat police-like in approach. But the opinion of the field auditor about any clinical investigator is not the sole criterion for judging the quality of the clinical trial and investigators have the freedom required to attend correctly to their patients in the American as well as the EC GCP system. In fact, there are few American guidelines; most GCP provisions are legal requirements to be found in the Code of Federal Regulations (referenced in our article).

This lack of basic understanding makes it hard to accept Wallnöfer and Cohen's criticisms [1], as they are not factually based.

We are well aware of the politicians' habit of putting words in another's mouth to float an argument, but expect better from scientists. Not only do we agree with the conclusion that things should be kept in balance, we said it first. There is plenty to criticise in GCP but, taken in balance, it provides a way that good and valid data can be obtained from clinical trials and permits sound conclusions about the efficacy of a medicine. Criticism should not be based upon the misquotation of articles that perhaps have not been read nor on a misunderstanding of the purpose of an official document. We hope this letter will put the record straight.

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References

- 1 Wallnöfer AE, Cohen AF. Good clinical practice: a question of balance. *Br J clin Pharmac* 1993; **35**: 449–450.
- 2 Allen ME, VandenBurg MJ. Good clinical practice: rules, regulations and their impact on the investigator. *Br J clin*

Pharmac 1992; **33**: 463–465.

- 3 Allen ME. *Good Clinical Practice in Europe*. Investigator's Handbook. Romford, Essex, Rostrum Publications, 1991.

Reply

We appear to have enraged Drs Allen and VandenBurg with our recent article [1]. This was unintended as we were trying to provide a model for collaboration. We did not criticise Good Clinical Practice guidelines as we particularly emphasized their importance in our article.

We referred to sections of publications of Allen and VandenBurg [2, 3] as an example of a confrontational attitude which may cause conflicts in the implementation of GCP. This may be clarified by some quotes from the book by Allen [3].

'—There are a number of games that can be played [by the investigator] to impede change.

—An investigator may delay, go on holiday, and do everything else to delay the start of the study.

— . . . He or she may have the same patients in more than one study at a time and think no one will notice.

—An investigator may not provide follow-up information when the company asks for it . . . , but then will fight to present the work at a conference in Miami.'