

CORRESPONDENCE

Clinical trials: a matter of principle

While I wholeheartedly support the sentiments expressed by Dr Gulhati in his editorial (1), I have reservations about the data cited and the manner in which they are presented.

Dr Gulhati cites several examples of unethical human research. There is not a single reference given in support of these 'facts'. It is possible that these data are factual; yet, without appropriate reference to the source, these examples become mere opinions.

Moreover, in an academic journal, the facts should speak for themselves, there should be no hyperbole. There are many differences between the USA and India. Stating that '...women have been treated worse than animals in America' serves no purpose.

The examples of poor protocols for drug trials that were approved by the DCGI also do not cite references. One must assume that these are based on personal communication to the author and the reader has to accept these assessments at face value. In the last paragraph, he writes: 'No wonder American companies have found doctors in Vietnam as competent as those in India in this field'. The implication here is that Vietnamese doctors are inferior to Indian ones. This smacks of cultural chauvinism.

I wish the author had given concrete suggestions for improving oversight in research trials and ways to decentralise the process so that it becomes more transparent and accountable.

I have come to expect higher academic and literary standards from the *Indian Journal of Medical Ethics* and hope the editors will sustain these principles.

Reference

1. Gulhati CM. Needed: closer scrutiny of clinical trials. *Indian Journal of Medical Ethics*. 2004;1:4–5.

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The author clarifies

All the cases of illegal (not merely unethical) drug trials cited in the article have been widely reported in the highly circulated print and electronic media. References are required for scientific articles where data are being quoted or interpreted and not to support the occurrence of events or while reporting plain news. Besides, none of the sponsors or investigators have raised any objection to the factual part of these press reports.

Webster's unabridged dictionary defines 'hyperbolic' as 'exaggerating or diminishing beyond the facts or exceeding the truth.' Not one word in the article meets this definition. I may add here that several newspapers such as the *Hindustan Times*, *The Indian Express* and *Business Standard* have picked up large portions from this article to focus the nation's attention on the malady of illegal and unethical drug trials. They have used exactly the same language as I did.

How can there be 'references' for poor protocols? The quoted protocols have been examined and reported in the article.

Foreign sponsors have been publicly arguing that drug trials require 'competent investigators, efficient infrastructure (research hospitals with world-class laboratories) and multi-ethnic patients' in support of their reasons for selecting India as the base for clinical trials. The real reasons are of course different: lower costs, lax implementation of laws and abundant availability of poor, illiterate patients. My reference to Vietnam is to show the hollowness of the sponsors' claims. Vietnamese doctors may be good clinicians but they do not have the infrastructure for drug trials comparable to those in India. Besides, there is only one ethnic population. Why, then, are American companies conducting drug trials there?

In an editorial, it is not possible to cover all aspects of drug trials such as improving the oversight functions. In any case, the Central Government is moving in the reverse direction: the new Schedule Y that governs trials is being 'liberalised', so that it would be easier to conduct trials in future.

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Bashir Mamdani's rejoinder

In his response, Dr Gulhati's states that his article did not deal with scientific content and therefore did not need to give scientific references; that newspaper accounts of deaths in the trials were adequate proof of something wrong happening in the trial; that newspapers have their own rules and regulations for responsible reporting.

I fully sympathise with Dr Gulhati's aims to bring greater scrutiny to research trials but I differ with him on how one should go about it.

I hesitate to rely on newspaper accounts for proof of wrongdoing as they are often incomplete and inaccurate.