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Human guinea pigs

A well-documented report examines clinical trials conducted outside Western countries, particularly in India, South Africa, China, Nigeria and Thailand (a,b)(1). The authors reported numerous abuses, especially of an ethical nature, and list the reasons drug companies increasingly prefer to test their products in these countries, either directly or by proxy through so-called contract research organisations.

Increasing number of trials in Asia, Africa and Latin America. Clinical trials are cheaper to conduct in these countries, mainly due to more rapid patient recruitment. Indeed, patients are more numerous and it is easier to convince them to enrol in clinical trials, especially when it represents their only access to treatment. They also have more symptoms because they have not received treatment, and are also “treatment-naïve” (with no other ongoing treatment), making trial results easier to interpret. They are also far less likely to drop out of ongoing trials, often because they are not even aware that this is an option. Trial results are therefore not weakened by large numbers of dropouts.

Finally, local authorities often see clinical trials as an opportunity to benefit financially (1).

Universal standards of ethics. Ethical issues are the same worldwide. And, in any given country, the fact that participants give their “informed consent” does not necessarily make the study ethical. Placebo-controlled

trials of me-toos, for example, are inherently unethical, as some patients are deprived of an existing beneficial treatment (1).

One Indian commentator, enthusing over the economic activity that clinical trials represent for his country, revealingly declared: “Best of all, this is one sort of outsourcing which American workers aren’t likely to protest” (2).

This is regrettable, to say the least. Patients and healthcare professionals in industrialised countries should be sure that they are only using drugs that have been tested in trials meeting the highest ethical standards.

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a- This work includes a preface by John le Carré, who wrote a thriller that revolves around abuses committed during trials conducted in poor countries (ref 3).

b- Two Dutch nongovernmental organisations have listed 22 trials (some of which were conducted in the West) that flout the Helsinki Declaration (ref 4). See references 5 and 6 for details on the protection guaranteed by the Helsinki Declaration to participants in clinical trials.

Selected references from Prescrire’s literature search.

- 1- Shah S “The Body Hunters: How the Drug Industry Tests its Products on the World’s Poorest Patients” New York, The New Press 2007 ; 256 pages.
- 2- Shah S “Délocalisation des risques. Médicaments du Nord testés sur les pauvres du Sud”. www.monde-diplomatique.fr accessed 23 January 2008: 6 pages.
- 3- Le Carré J “The Constant Gardener” Hodder & Stoughton, London 2001 ; 570 pages.
- 4- SOMO and Wemos “SOMO briefing paper on ethics in clinical trials - Example of unethical trials” 2006. www.wemos.nl accessed 16 November 2007: 16 pages.
- 5- Prescrire Rédaction “Expérimentation. Déclaration d’Helsinki de l’Association médicale mondiale” *Rev Prescrire* 2001; 21 (219): 542-543.
- 6- Prescrire Rédaction “Recherche biomédicale: l’intérêt des personnes d’abord” *Rev Prescrire* 2001; 21 (219): 539-540.

