

Call for Ethical Clinical Trials in Developing Countries

The logo for Fair Drugs.org features a teal circular outline. Inside the circle, the text "Fair Drugs.org" is displayed. "Fair" and "Drugs" are in a teal, sans-serif font, while ".org" is in a smaller, green font.

Fair Drugs.org



Sign the Call for Ethical Clinical Trials in Developing Countries:
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Introduction

Before a new drug can be released onto the market, it has to be tested on human subjects in order to assess its efficacy and safety. Increasingly, the pharmaceutical industry is carrying out these trials in developing countries.

For pharmaceutical companies, lower costs are an important reason to undertake trials in developing countries. Trials can also be carried out more quickly because regulatory constraints are less stringent, while the low level of income in developing countries means that people are often more willing to participate. However, there are good reasons to believe that trial subjects in these countries are more vulnerable than those in wealthier nations.

Firstly, the health systems in developing countries often function inadequately, leaving the poor without access to essential treatment. As a result, poorer citizens in need of medical attention may find themselves forced to participate in a trial. In addition, the end of a drug trial often means the end of all treatment, entailing serious risks for the trial subjects.

Secondly, one of the most fundamental requirements for clinical trials is that subjects are well informed in advance about the nature of the trial and the potential risks involved. Any agreement to take part must be voluntary. However, poverty, illiteracy, a hierarchical doctor-patient relationship and lack of access to treatment make this difficult to guarantee.

Thirdly, the care providers who carry out clinical trials in developing countries have not always followed the training needed to conduct such trials according to ethical standards. Furthermore, conflicts of interest may occur when doctors involved in clinical trials are paid large sums of money to recruit patients.

International guidelines have been formulated to protect the rights of trial subjects. These include the [Nuremberg principles](#), the [Declaration of Helsinki](#) and the Council for International Organizations of Medical Sciences (CIOMS) [International Guidelines for Biomedical Research](#).¹ However, trial sponsors do not always adhere to these guidelines and, in many cases, the bodies charged with overseeing and implementing these guidelines in developing countries, such as regulatory agencies and ethics committees, do not function properly.



Common ethical violations include:

- Trial subjects not being well informed in advance about the nature of the trial and the risks involved;
- Trial subjects not being guaranteed continuing treatment when the trial has ended;
- Failure to have the ethical aspects of the research proposal approved by a local ethical review committee prior to the start of the trial;
- The experimental drug being tested against a placebo instead of the current proven intervention;
- Failure to ensure that the population involved in the trial benefits from the results of the research.

Increasingly, the drugs sold in the European Union (EU) have been tested in developing countries. The European Medicines Agency (EMA) and the national medicines agencies charged with the approval of new drugs and their admission to the EU market perform only very limited checks on whether these drugs have been tested according to ethical guidelines.

The following statement, which has been signed by leading figures in the field of medicine and ethics and others concerned about the issue, is a call to action for policy makers, regulators and pharmaceutical companies.



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1. Trial subjects, wherever they live, are entitled to clinical trials that are conducted in accordance with the ethical principles for medical research involving human subjects laid down in the most recent version of the [Declaration of Helsinki](#).
2. As purchasers of drugs tested in developing countries, EU Member States have a responsibility towards the people on whom these drugs have been tested.
3. [European Commission Directive 2003/63/EC](#) already states that clinical trials conducted outside the European Community will only be taken into account during the assessment of a drug application if they have been carried out in accordance with ethical principles such as the Declaration of Helsinki.
4. Research indicates that the European Medicines Agency and equivalent national bodies are not carrying out the ethical checks required by Directive 2003/63/EC.^{2,3}
5. As a result, drugs that have not been tested according to ethical standards are entering the EU market.⁴
6. We call on the European Commission and EU Member States to:
 - a. Ensure the European Medicines Agency and national medicines agencies perform the required ethical checks and ensure they have access to the required information such as Good Clinical Practice audit reports;
 - b. Apply sanctions against pharmaceutical companies and other sponsors of clinical trials that engage in unethical drug testing;
 - c. Oblige pharmaceutical companies and other sponsors of clinical trials to register all relevant information in a publicly accessible register according to the guidelines set out by the World Health Organization's [International Clinical Trial Registry Platform](#).
7. We commend the European Commission and EU Member States for supporting capacity building related to clinical trials in developing countries. They should continue to provide the resources needed to ensure that the regulatory bodies and ethical review committees in developing countries are able to function and that health workers are trained to carry out clinical trials to required standards.

8. We call on the European Medicines Agency and the national medicines agencies to:
 - a. Develop tools to better assess the ethical aspects of clinical trials, in consultation with experts from developing countries;
 - b. Routinely seek access to information on the ethical aspects of trials from pharmaceutical companies.

9. We call on governments of the countries in which clinical trials are being carried out to:
 - a. Ensure that trial sponsors adhere to the ethical principles laid down in the Declaration of Helsinki;
 - b. Strengthen their own regulatory bodies and ethical review committees to achieve this objective.

10. We call on pharmaceutical companies and other trial sponsors to:
 - a. Demonstrate that any clinical trials undertaken in developing countries are conducted in an ethical manner, including those trials which are outsourced to a Contract Research Organization (CRO);
 - b. Make drugs available and affordable to the population from which the trial participants were drawn.

Endnotes

1. Other guidelines are the Guidelines for [Good Clinical Practice \(GCP\) for Trials on Pharmaceutical Products](#) (World Health Organization, WHO); the [Buenos Aires Declaration on Ethics and Clinical Trials](#); the [Universal Declaration on Bioethics and Human Rights](#) (United Nations Educational, Scientific and Cultural Organization, UNESCO); and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) [Tripartite Guideline for Good Clinical Practice](#).
2. Centre for Research on Multinational Corporations (SOMO). 2008. [Ethics for Drug Testing in Low and Middle Income Countries. Considerations for European Market Authorisation](#).
3. Wemos. 2007. [Do European Registration Authorities ascertain whether Clinical Trials in Developing Countries have been conducted in an Ethical Manner?](#)
4. Centre for Research on Multinational Corporations (SOMO). 2008. [Ethics for Drug Testing in Low and Middle Income Countries. Considerations for European Market Authorisation](#).



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