A BITTER PILL

The risks of carrying out clinical drug trials in developing countries

wemos

In this information booklet, the Wemos Foundation describes the risks involved when carrying out clinical drug trials on the inhabitants of developing countries, and puts forward concrete proposals for the improved protection of these vulnerable test subjects.

The Wemos Foundation is an Amsterdam-based organization contributing to the structural improvement of people's health in developing countries through advocacy.

Contents

Preface

For many decades those working in the fields of medical ethics and health law have devoted considerable attention to the question of research into the effects of new drugs on human beings. Many countries, including all members of the European Union and the United States, have put in place extensive legislation to protect 'test patients', for the most part people suffering from an illness and who are given the new drug as part of an experimental treatment. At the heart of all these legislative frameworks is the requirement that such patients must have given their prior, voluntary and informed consent, and may not under any circumstances be exposed to harm. This issue continues to warrant our watchfulness and concern; in practical terms it means that every clinical trial ought to be subjected to the scrutiny of an ethical review committee.
For many years Wemos has closely examined the clinical drug trials that are carried out in developing countries by Western pharmaceutical companies. To my mind it is self-evident that these trials ought to be subject to the same ethical regulation framework as they are in the West. We must continue to discuss with politicians, policymakers and the pharmaceutical industry: are the relevant standards and regulations being adhered to? Which bodies monitor compliance? And is their supervision adequate to the task? Of course, clinical drug trials everywhere are necessarily accompanied by a certain level of risk to the participants. However, in my view we are faced with a serious problem. The West has such a voracious appetite for new and improved drugs that it sometimes seems justified to make these available at any cost. It would be mistaken to claim that the pharmaceutical industry alone is responsible for this; the matter concerns us all.
One principle, however, does apply everywhere and in all cases: the ancient Hippocratic injunction to 'do no harm'. This does not mean that nothing will ever turn out unfavourably, but it clearly means that we must always do our best to prevent harm. And we must continue to urge each other to do the same, as is the case in this document.

Dr. Heleen Dupuis
Professor of Medical Ethics and member of the Dutch Upper Chamber of the States General

1. The move to developing countries

Pharmaceutical companies are increasingly testing new drugs on people in developing countries, because it is less complicated and much cheaper than doing this in the West. However, the pharmaceutical industry does not always undertake these clinical trials in an ethically responsible way.

Experiment

Imagine for a moment that you live in a developing country and are seriously ill. Treatment in the nearest hospital is too expensive. You hear that a hospital 100km further away provides free medicines, so you go there. You are given a medicine, provided you return twice a week for examination. Later on you hear that the medicine is an experimental one, the long-term effects of which are still largely unknown. The doctor who saw you had not told you this when you first came for treatment. What he does now tell you is that the clinical trial of which you were a part will soon be concluded, and that the drug that was used will no longer be available to you. No alternative medicine will be provided, either. Even if the company producing the drug, a Western pharmaceutical firm, were to market the drug in your country, it would cost much more than you could afford.

Testing on people

Before a new drug can be released onto the market it has to be tested on people in order to assess its therapeutic value and side effects. Increasingly, the pharmaceutical industry is carrying out these trials in low-wage and developing countries. Eastern Europe, Asia, and Central and South America are particularly popular destinations, but South Africa is also seeing more and more clinical trials. The drugs being tested are often medicines that are destined for consumption in lucrative Western markets; relatively little research is being done on drugs that might assist local populations, such as drugs that might alleviate the diseases borne of poverty.

Trial supervision is often the responsibility of a Contract Research Organization (CRO); this can save the pharmaceutical company money, for instance on staffing costs. However, the contracting pharmaceutical firm remains ultimately responsible for the methods employed.

Clinical trials

A new drug has to go through a number of trial phases before it is registered, or 'filed', with the relevant authorities as a marketable medicine. During the clinical trial phase, which comprises four stages, the drug is tested on people.

Phase 1: The drug is tested on a few dozen healthy people or, if the drug is known to have serious side effects (as do cancer drugs), on patients. Studies are made of the drug's safety and side effects on the human body.

Phase 2: The drug is administered to a few hundred patients. The pharmaceutical delivery form (tablet, injected fluid) is further researched, together with the drug's therapeutic effectiveness and side effects.

Phase 3: The drug is administered to several thousand patients and its therapeutic effectiveness assessed. These trials are randomized and double-blind. 'Randomized' means that the test subjects are randomly allotted to one of two groups, one of which is given the drug and the other a harmless, non-active placebo; 'double-blind' means administering drugs in such a way that neither doctor nor patient knows which individuals are in which group.

Phase 4: After a drug has been approved for marketing, in certain cases its use is followed up for a certain period of time in order to discover whether any hitherto undetected, atypical, and serious side effects appear over the longer term, and also whether the drug might be applicable to other medical conditions.

Shift

Several reasons can be advanced to account for the general shift in many clinical trials away from the West and towards developing countries.
As far as the pharmaceutical industry is concerned:

- Doing clinical trials in developing countries is 10-50% cheaper;
- Regulatory constraints in developing countries are either less stringent or less actively policed. Research protocols can therefore be approved more easily, trials can be carried out more quickly, and drugs can be brought to market more quickly. This is an attractive proposition when the 20-year drug marketing monopoly which a patent confers to a pharmaceutical company starts from the date of patent registration;
- It is easier to find test subjects in developing countries, because participation in a trial is often the only treatment option, or because it offers the chance to make some money. Many developing countries (such as India) have large populations, which makes it easier to find patients suffering from a given disease, even if this disease is comparatively rare;
- Test subjects in developing countries have less frequently already been exposed to similar medicines, and this improves the reliability of the test results.

The governments of developing countries are also interested in the economic benefits of allowing clinical trials to be carried out in their countries. The Indian government actually rewrote national law to make life easier for pharmaceutical companies, and in 2010 an estimated two million people will be taking part in clinical trials there, bringing about €1.2 billion into the Indian treasury.[1] The pharmaceutical industry has even threatened to halt trials in Western countries such as the Netherlands whose comparatively stringent regulatory frameworks are perceived as a stifling constraint.

Finally, fewer and fewer people in Western countries appear to be prepared to take part in clinical trials, partly as the result of negative publicity. An example of this publicity would be the 2006 trial of an experimental drug for the treatment of chronic infection and leukaemia, which led to six British men falling seriously ill.[2]

No figures, no transparency

It is impossible to state with any certainty how much of their clinical trials pharmaceutical companies currently carry out in developing countries. The managements of companies such as GlaxoSmithKline, Wyeth Pharmaceuticals and Merck have given percentages varying from 29% to 70%.[3] Scientists have suggested that 40% of the total number of clinical trials are taking place in so-called 'non-traditional research areas'.[4] The reason that these figures are uncertain is that there exists no universal, compulsory registration system for these trials; nor is there any centralized, recognized, supervisory body. It is therefore impossible to know how many trials are taking place, where they are being held, or what methods are being used. Although a number of pharmaceutical companies do post information on the internet, they are not formally obliged to publish it at all. This means that comparable clinical trials could be carried out at the same time by different companies, thereby exposing an unnecessarily high number of test subjects to the same risks. Pharmaceutical companies are not obliged to publish the results of their trials, either, and this means that trials having negative outcomes are less frequently published.[5]

Critical scrutiny

The Wemos Foundation closely follows the activities of the pharmaceutical industry in carrying out clinical drug trials in developing countries. This is because research has shown that the industry has not been unstintingly assiduous in adhering to the international codes and guidelines that apply (see box). In 2006, SOMO *(Stichting Onderzoek Multinationale Ondernemingen)* and Wemos jointly published a report detailing 22 cases of unethical trials on human subjects.[6] A number of other news media, including the Dutch documentary television programme Netwerk, the Dutch national newspaper *NRC Handelsblad* and the *British Channel Four*, have reported on the abuses surrounding clinical trials in developing countries.[7,8,9] Wemos partner organizations in Asia and Latin America have confirmed these problems. The lack of transparency in clinical trials means that it is also impossible to say whether these problems are structural in nature, but the Wemos Foundation is of the opinion that the problem is more than incidental and is engaged in ongoing research to substantiate its claim.

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Relevant legislation

The first ethical guidelines for clinical trials date from 1947 and the Nuremberg Code. Today the Declaration of Helsinki is held to be the most authoritative document. The Declaration deals exhaustively with the ethical principles of medical research on human subjects, detailing the importance of voluntary, informed consent; the fact that the interests of the subject are higher than those of the research; and the requirement that patients have post-trial access to treatment.[10]

There also exists a number of Guidelines for Good Clinical Practice, including those of the World Health Organization (WHO), which have set globally applicable quality standards for the construction, execution, monitoring, documentation and reporting of clinical trials, with frequent reference to the ethical principles set out in the Declaration of Helsinki.[11]

In addition, in order to be admitted to the European market a drug has to have been tested in accordance with European Union guidelines called 'directives';[12] if they were not, the pharmaceutical company can actually have its trading permit refused or revoked. The courts can also institute civil or criminal proceedings against such a company (see for example 'Medicine for meningitis' on page 12/13).

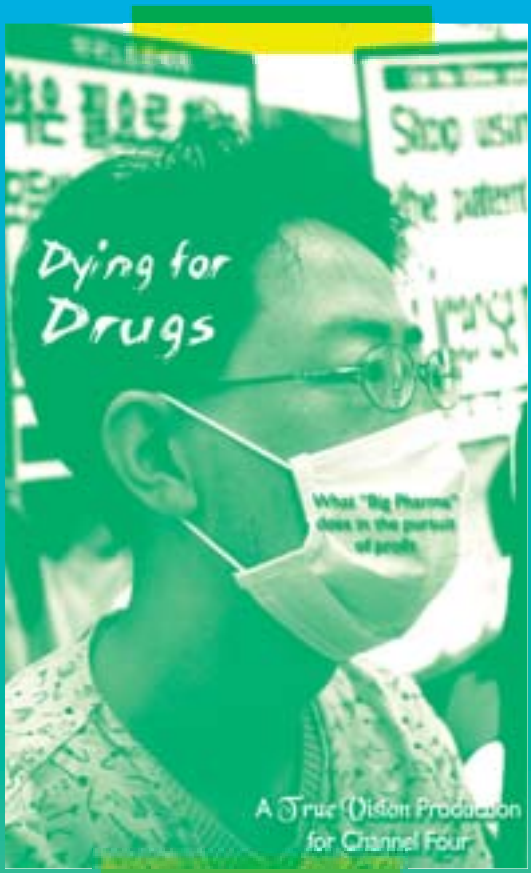
An example: medicine for meningitis

'They told us nothing about the medicine, only that they wanted to help the children,' explains Anas' father. Anas is one of the 200 children who was given free medicine by the pharmaceutical firm Pfizer during an outbreak of meningitis in Kano (Nigeria) in 1996; his father appears in the 2003 documentary film *Dying for Drugs*.[13] 115,000 people were infected during the epidemic, and 15,000 died. Of the 200 Nigerian children who took part in a trial of the experimental antibiotic Trovan, eleven died. Others were paralyzed or suffered brain damage. Anas survived the epidemic, but his knee hurts every day, and the question is whether this pain is the consequence of the disease or of its treatment by Pfizer.

In *Dying for Drugs* and in research carried out by SOMO *(Stichting Onderzoek Multinationale Ondernemingen)*, Pfizer turns out to have failed to ask the children's parents in advance for permission to use this treatment; they also failed to inform the parents that the treatment was experimental. This is all the more reprehensible when one learns that a conventional treatment was not only available but was actually being distributed in the same area by the medical aid organization Doctors without Borders. Neither had the research protocol been approved by an ethical review committee.

In *Dying for Drugs* it is suggested that Pfizer forged approval documents. In July 2007, the Nigerian government brought charges against Pfizer, demanding €1.94 billion in damages. Pfizer rejected all accusations, claiming that the trials were carried out responsibly, that the drug had saved lives, and that the required parental permission had been obtained by word of mouth through a local nurse. No direct link between the children's deaths, the medical complaints they suffered, and their participation in the trial has yet been obtained. Nevertheless, it is known that the drug has serious side effects, and for this reason it is not currently being marketed in Europe.

The court case has been postponed several times to give the plaintiff more time to prepare, and in October 2007 the case was due to be resumed in November 2007.[14]



Dying for Drugs is available from www.truevisiontv.com.

2. Vulnerable test subjects

Participating in clinical trials invariably involves a risk; but there are good reasons to believe that the rights of test subjects in developing countries are less secure than those of their counterparts in the West.

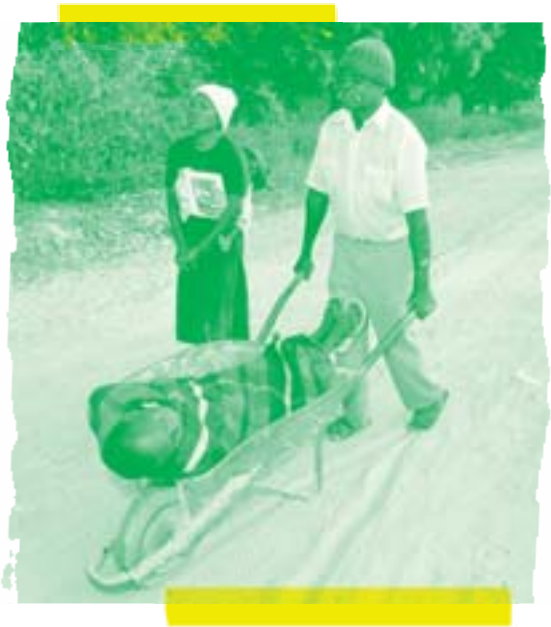
Inadequate care

The Universal Declaration of Human Rights states that everyone has the right to a standard of living adequate for the health of himself and of his family. This means that everyone in the world should be able to enjoy the conditions necessary to guarantee a healthy and productive life, which would include accessible and affordable health care. In practice, however, health systems in developing countries are far from ideal, and this means that test subjects in these countries are more vulnerable.

In developing countries the end of a drug trial often also means the end of any treatment at all, even though this is in direct contravention of the Declaration of Helsinki demanding that test subjects be guaranteed continuing treatment. To make matters worse, by the time most medicines are brought onto the market they are far too expensive to be afforded by any of those on whom they were actually tested.

Another problem is formed by the shortage of well-trained medical personnel. Care providers in developing countries have not always had the training needed to carry out clinical trials to the required standards.

Clinical trials can also lead to work overload and the consequent inability to fulfil existing, routine work commitments.



Dubious permission

One of the most fundamental demands of clinical trials made in the Declaration of Helsinki is that test subjects are well informed in advance on the nature of the trial and the risks entailed; any agreement to take part must then also be voluntary. In developing countries, poverty, illiteracy, a strongly hierarchical relationship between doctor and patient, and utter dependence on the treatment being offered make this difficult to guarantee.

The payment offered for participation in clinical trials can form a powerful incentive for people who are living in poverty. Many are only too happy to take the money irrespective of the risks. This applies not only to the test subjects but also to the doctors carrying out the trial, who stand to profit from putting as many patients forward as possible.

Other examples of such abuse can be found in the information material provided. For instance, in Cameroon-based trials of a drug that was hoped to reduce the rate of HIV transfer from mother to child, information leaflets were provided to test subjects – but not in their own language.[15]

Inadequate ethical checks

Responsibility for checking the ethical aspects of research proposals for clinical trials lies principally with ethical review committees in the developing countries. It is their job to ensure that test subjects are not exploited and that the trials are carried out in accordance with the regulations. However, research has shown that these committees are frequently unable to adequately perform this work. In 2004, for instance, the results were published of a study (commissioned by the American National Bioethics Advisory Committee) among 200 researchers. It concluded that fully a quarter of the clinical trials taking place in developing countries had not been subjected to prior ethical assessment. A 2005 study by the Indian Council of Medical Research revealed that less than a quarter of all Indian ethical review committees followed the prescribed guidelines, and that in half of all such committees possible conflicts of interest could not be ruled out.[16]

In some countries the relevant legislation is weak. India, for instance, has good ethical guidelines for clinical trials, but it does not have the corresponding legislation needed to enforce them in law. Where adequate legislation does exist, such as in South Africa, there can be considerable variation in the effectiveness of local ethical review committees.

Pharmaceutical companies can therefore select 'easier' committees to consider the more 'difficult' of the proposed research protocols. National standards by which an overseeing organization can assess the quality of ethical review committees have existed since 2002, but their influence on the actual quality of clinical trials in South Africa remains unclear.[17]

There are good reasons to believe that the rights of test subjects in developing countries are less secure than those of their counterparts in the West.

Inadequate checks in Europe

It is important to keep watch on the quality and independence of the work carried out by local ethical review committees. Ideally this is done by the governments of the countries in which the trials are being carried out, but in practice this is seldom the case, either because these governments are ill-equipped to undertake such activities or because they do not possess the relevant information. To ensure that unethically tested medicines do not reach the market, and that pharmaceutical companies do not earn large sums of money despite having violated the regulations, it is necessary that other bodies, for instance the European Union (EU), perform stringent checks of their own. As a major purchaser of drugs tested in developing countries, the EU has a clear responsibility towards the test subjects on which these drugs have been tested.

The bodies charged with the approval of new drugs and their admission to the EU market are the London-based European Agency for the Evaluation of Medicinal Products (EMEA), and the national registration authorities of each EU member state; for instance, the relevant body in the Netherlands is the CBG *(College ter Beoordeling van Geneesmiddelen)*. The Wemos Foundation has carried out research into whether these bodies do indeed establish whether a new drug was tested in accordance with ethical guidelines.[18] The results of this research were that the registration authorities:

- performed only very limited checks of whether clinical trials in developing countries had been carried out ethically;
- accorded a large part of the responsibility for adherence to ethical guidelines to the ethical review committees in the developing countries where the trial was carried out, but almost never investigated whether the composition and working methods of these committees met the requirements for good medical research.

The research also showed that when a drug was found to have been tested unethically, this did not necessarily have negative consequences for its admission to the European market.

An example: a new type of stent

On 26 April 2006, the Dutch documentary television programme *Netwerk* reported that a Dutch medical equipment producer, the Eindhoven firm Occam International, had tested an experimental stent on about 70 Indian heart patients, without telling them that this was part of a test. Neither had there been any approval from an ethical review committee.

The special stent, a tube that holds open congested coronary arteries and also delivers a medicine, was then admitted to the Dutch market by TNO *(Nederlandse organisatie voor toegepast natuurwetenschappelijk onderzoek)*. TNO claims that this marketing permission was not based on the research documented in the *Netwerk* programme, but refuses to say on which research it was based. 'If I'd known what they were up to, I would never have agreed,' says Mr Bahadur Gurung, one of the heart patients interviewed in the *Netwerk* documentary. A conversation between *Netwerk* and two Indian cardiologists who were involved in the clinical trial showed that a deliberate decision had been made not to ask for permission, in order to circumvent the

complicated and time-consuming ethical procedures that surround clinical trials.
A number of patients who had assumed that they were receiving conventional treatment are now demanding damages from Occam for having been used as guinea pigs without their knowledge – and also for having had to pay a large sum of money to have the stent implanted, despite the fact that such payments are explicitly forbidden by the regulations governing clinical trials. Both Occam and the participating Indian hospital in Mumbai have denied carrying out clinical trials, but *Netwerk* showed documents and broadcast recordings which make it clear that these activities were indeed experimental.
The Dutch IGZ *(Inspectie voor de Gezondheidszorg)* carried out research into this issue, but concluded that clinical trials carried out abroad fell outside its jurisdiction. It did, however, describe the company's practices as unprofessional and amateuristic.[19] Hans Hoogervorst, the then Minister of Health, Welfare and Sport of the Netherlands, added that he found it reprehensible that 'in having failed to ask for their permission, or by having withheld essential information, misuse was made of the vulnerable position of patients and test subjects'.[20]

To see the Netwerk documentary on Occam (in Dutch), go to www.netwerk.tv, click on 'Archief', '2006' and 'April' (see 'dinsdag 25 april' and 'donderdag 27 april') and 'September' (see 'donderdag 28 september').

'If I'd known what they were up to, I would never have agreed.'

3. Ethical testing

Wemos deems it unacceptable that the rights of test subjects in developing countries are abused. Wemos works to promote 'fair' drugs, medicines which have been ethically tested.

Stricter checks in Europe

As far as 'fair' drugs are concerned, Wemos feels that greater priority should be given to stricter European checks. EMEA and the various national registration authorities must carry out thorough checks, to prevent unethically tested drugs from being admitted to the European market. Wemos also points to a safety factor: unethical testing increases the unreliability of research results and consequently the risk of unsafe medicines. Wemos is in ongoing consultations with EU ministers, the representatives of European registration organizations, the pharmaceutical industry, civil society organizations, civil servants and professional experts on the measures that could be taken.

Stronger health systems

The construction and strengthening of health systems in developing countries is the joint responsibility of the governments of the developing and the aid-giving countries. Wemos lobbies for adequate staffing levels; training for health personnel involved in clinical trials; the safeguarding of continued medical treatment after the conclusion of drug trials; and the marketing of affordable drugs in the countries in which they were tested.

Better inspection in the countries involved

Stricter controls by local ethical review committees form part and parcel of a solid health system. Their capacities, in terms of manpower, skills, financial resources, and so on, must be improved. Wemos sees a role here for Western aid investors. Other important measures would include the improved supervision of adherence to ethical guidelines by national governments, professional medical groups, and local civil society organizations. In some countries it might be necessary to introduce stricter national legislation.

More transparency

The current lack of transparency in regard to the registration of clinical trials with international databases and to the publication of their results impedes their effective scrutiny by governmental or civil society organizations. Wemos argues for the compulsory registration by pharmaceutical companies of such trials in a publicly accessible register, in accordance

with WHO guidelines. Scientists, science journalists, professional experts and a number of pharmaceutical companies have all urged for the improvement of transparency.[21]

Responsible behaviour from the industry

The Wemos Foundation calls on pharmaceutical companies to adhere to the current regulations on the ethical testing of drugs on human beings, as set out in the Declaration of Helsinki, the WHO's Guidelines for Good Clinical Practice, and on new, binding European legislation. The pharmaceutical industry has taken a number of laudable initiatives; for instance, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) launched a Clinical Trials Portal in 2006, in a move to contribute towards improved transparency. The Portal is an online database of information on current and completed clinical trials.[22] However, the IFPMA does not make all sections of the database available until the drug concerned has been registered, so the system fails to provide complete transparency.[23] This means that no supervision can be undertaken (for example, by civil society organizations) of the research protocol construction and the degree to which attention has been given to ethical aspects.

Wemos works to promote 'fair' drugs.

Tjalling van der Schors, hospital pharmacist, member of the Medical Ethical Review Committee of Westfries Gasthuis (hospital in Hoorn, the Netherlands), and connected with Stichting Farmacie Mondiaal.

Unethical means unsafe

'I am not sure whether clinical trials should be carried out in developing countries at all. They put a strain on limited medical resources, such as doctors and medical knowledge, for purposes that do no primarily serve the population of the country in question.

If these trials are nonetheless carried out, but in an unethical manner, then I think that their results should be inadmissible for the purposes of European registration, because of the safety risks. If a company ignores the regulations and offers doctors unusually large sums of money in return for their participation in clinical trials, then we have no guarantee that the work will be carried out to the highest standards of independence and reliability.'

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Abbreviations

CBG	*College ter Beoordeling van Geneesmiddelen* (Medicines Evaluation Board)
CRO	Contract Research Organization
EMEA	European Agency for the Evaluation of Medicinal Products
EU	European Union
HIV	Human Immunodeficiency Virus
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGZ	*Inspectie voor de Gezondheidszorg* (Health Care Inspectorate)
NCDO	*Nationale Commissie voor Internationale Samenwerking* en *Duurzame Ontwikkeling* (National Committee for International Cooperation and Sustainable Development)
SOMO	*Stichting Onderzoek Multinationale Ondernemingen* (Centre for Research on Multinational Corporations)
TNO	*Nederlandse organisatie voor toegepast natuurwetenschappelijk onderzoek* (Netherlands Organization for Applied Scientific Research)
WHO	World Health Organization

More information

Would you like to stay informed about Wemos and its Medicines project? Visit www.wemos.nl for more information and sign up for Wemos' free e-newsletter (in Dutch).

Dr. Amar Jesani, Coordinator of the Centre for Studies in Ethics and Rights, Mumbai, India.

The patients are the victims

'Many doctors in India involved in clinical trials are given enormous sums of money in return for recruiting patients. This leads to a conflict of interests, of which the patients are the victims. When they find they need medical attention, the financial obstacles they encounter tempt them to close their eyes to the possible risks of clinical trials. Moreover, a large part of the Indian population is illiterate, unable to understand the information provided in advance of a trial, and therefore unable to give informed consent. In the meantime their doctor is generally urging them to take part. So they end up in a clinical trial without ever having properly understood the risks.'

About this publication

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