

# Ethics of clinical trials in Nigeria

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## ABSTRACT

The conduct of clinical trials for the development and licensing of drugs is a very important aspect of healthcare. Drug research, development and promotion have grown to a multi-billion dollar global business. Like all areas of human endeavour involving generation and control of huge financial resources, it could be subject to deviant behaviour, sharp business practices and unethical practices. The main objective of this review is to highlight potential ethical challenges in the conduct of clinical trials in Nigeria and outline ways in which these can be avoided. Current international and national regulatory and ethical guidelines are reviewed to illustrate the requirements for ethical conduct of clinical trials. Past experiences of unethical conduct of clinical trials especially in developing countries along with the increasing globalisation of research makes it imperative that all players should be aware of the ethical challenges in clinical trials and the benchmarks for ethical conduct of clinical research in Nigeria.

**Key words:** Clinical trials, ethics, Nigeria

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## INTRODUCTION

The conduct of clinical trials for the development and licensing of drugs is a very important aspect of healthcare. The need to develop more effective and safer drugs to tackle existing disease and also tackle new and emerging diseases cannot be over-emphasised. Drug research, development and promotion have grown to a multi-billion dollar global business. The global pharmaceutical market is expected to reach one trillion USD in 2014<sup>1</sup> and 1.3 trillion USD in 2020.<sup>2</sup> By far most of this revenue is generated and controlled by pharmaceutical companies with headquarters in Europe and North America. Recently though, companies from South America and Asia are gradually getting an increasing portion of the global pharmaceutical business.<sup>1</sup> Like all areas of human endeavour involving generation and control of huge financial resources, it could be subject to deviant behaviour, sharp business practices, unwholesome and unethical practices.

This review article looks at the ethical issues involved in clinical trials with emphasis on the Nigerian context in particular. The main objective is to highlight potential ethical challenges in the conduct of clinical trials in

Nigeria and outline ways in which these can be avoided. Current international and national regulatory and ethical guidelines are reviewed to illustrate the requirements for ethical conduct of clinical trials. To achieve this objective this article would review the phases in clinical trials; provide examples of clinical trials with questionable ethical conduct; discuss the various stakeholders in clinical trials, their respective interests and ethical concerns; and provide a benchmark for ethical conduct of clinical trials.

## PHASES IN CLINICAL TRIALS

Before pharmaceutical companies proceed to clinical trials, preclinical trials (*in vitro* and *in vivo* animal studies) would have been conducted to obtain data that would justify progression to clinical trials. Clinical trials are in four phases.

### Phase I

Phase I clinical trials are conducted on healthy volunteers. The objective is to establish the safety and toxicity profile of the test drug. It is also to study the pharmacokinetics and pharmacodynamics of the drug in humans.

### Phase II

Phase II clinical trials involve drug trials with a few number of patients that suffer the disease of interest. The objective is to establish efficacy of the test drug.

### Phase III

Phase III clinical trials involve conduct of drug trials with a large number of patients. It is usually an expanded and more focused studies of clinical effectiveness and safety.

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## Phase IV

Also called Post-marketing clinical trials. At this phase of clinical trial, drug has been licensed for treatment and its usage is continually monitored for adverse effects.

The vast majority of literature on clinical trials is mainly on Phase II and III trials; however, ethical concerns cut across all phases of clinical trials and also the preclinical phase involving animal trials.

## CLINICAL TRIALS WITH QUESTIONABLE ETHICAL CONDUCT

The literature on ethics of clinical trials of drug candidate is replete with notable instances of poor ethical conduct. The following two examples highlight some of the ethical pitfalls to be avoided.

### The AZT trials in African and other developing countries

The AIDS Clinical Trial Group (ACTG) in 1994 reported the findings of their study 076 in which the use of Zidovudine (AZT) during pregnancy, in labour and to the newborn reduced the mother to child transmission (MTCT) of HIV by two-thirds.<sup>3</sup> With this finding, use of oral AZT during pregnancy and intravenous AZT during labour and oral AZT to the neonate became the standard of care for HIV-positive mothers in the United States and Europe. However in Africa, where the burden of HIV was high, this regimen was considered unaffordable. The World Health Organisation summoned a meeting to discuss the conduct of research into finding less expensive and affordable interventions to prevent (MTCT) of HIV in developing countries. Subsequently a series of placebo-controlled trials were conducted in Africa and Asia. Many bioethicists have questioned the morality of using a placebo-controlled design in these studies. They argued, that with the results of the ACTG 076 study, the appropriate research question should be - 'Can we have a cheaper intervention compared with the standard ACTG 076 without compromising on the demonstrated efficacy of ACTG 076?'

Thus the study design would be an equivalence study with ACTG 076 being given as the control arm. But by using placebo-controlled design, the research question became, 'are these cheaper interventions better than nothing' or 'Is the short course of AZT better than nothing?'.<sup>4</sup> Ethicists argued that since a placebo-controlled trial would not be acceptable in developed countries (as AZT had become the standard of care), it smacked of moral imperialism and double standard to offer such to developing countries.<sup>5-9</sup> By conducting placebo-controlled trials of AZT in developing countries many neonates who would have been saved from contracting HIV infection if their mothers had been given the AZT rather than placebo were not saved.

## The Pfizer Trovan study in Nigeria

In 1996, there was an outbreak of cerebro-spinal meningitis in Tudun Wada in Kano State. Children were predominantly affected by the outbreak. The state government mobilised resources to combat the meningitis epidemic. Also, international organisations like the Medecins Sans Frontieres (MSF) were there to assist in treating patients. Pfizer brought in a team to conduct a research on its test drug TROVAFLOXACIN (TROVAN) - a quinolone antibiotic. Pfizer recruited a total of 200 children into the study in two arms- one arm had the test drug Trovan orally and the control arm was given Ceftriaxone or Chloramphenicol. Within 3 weeks of commencing the study the required numbers of participants were recruited and the study concluded.<sup>10</sup> The study was, however, criticised severely for falling short of ethical standards.<sup>11</sup> The allegations were that:

1. Pfizer never obtained ethical clearance before conducting the study;
2. Pfizer did not obtain informed consent before recruiting participant and did not inform the study participants that the drug was an experimental drug;
3. Pfizer capitalised on the poor, illiterate and desperate situation of the people; and,
4. Pfizer left the town after conducting the study despite the fact that the epidemic was still ongoing.<sup>11,12</sup>

The Government panel set up to investigate the study reached these conclusions:

Pfizer never obtained authorisation from the necessary authorising agencies including ethical clearance and that Pfizer's experiment was "...an illegal trial of an unregistered drug" and "a clear case of exploitation of the ignorant."<sup>12</sup>

Pfizer later agreed to a \$75 million out of court settlement.<sup>13</sup>

These two case studies illustrate some ethical challenges that may arise in the conduct of clinical trials. There are several ethical considerations that all key stakeholders in the conduct of clinical trials must make to ensure that clinical trials meet ethical standards.

## STAKEHOLDERS IN CLINICAL TRIALS, THEIR INTEREST AND ETHICAL CONCERNS

### Clinical trial sponsors

The United Kingdom clinical trial regulation defines the sponsor as, 'an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial'.<sup>14</sup> The code of federal regulation of the United States of America has a similar definition, 'A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, government

agency, academic institution, private organisation or other organisation'.<sup>15</sup>

In the Nigerian research environment the sponsors of clinical trials are usually the pharmaceutical companies and International Non-governmental agencies. Pharmaceutical companies are business companies and like all business companies, their main objective is to maximise profit while reducing cost of production. Conducting clinical trials in developing countries holds an attraction for pharmaceutical companies based in developed countries. Developing countries hold a large reservoir of diseases and the required number of patients can be recruited within a short duration. Also, compensation for lost time and wages paid to research participants in developing countries is small compared to what is payable to research participants in developed countries. The requirements for approval of such studies in developing countries is usually a lot less stringent compared to the requirements in developed countries.

However, there are considerable ethical challenges associated with international clinical trials in developing countries with sponsors from developed nations. Such ethical challenges include:<sup>16</sup>

1. Justifying the medical and social relevance of the clinical trials to the host community.
2. The quality of informed consent
3. The standard of care
4. Post-trial availability of interventions

These ethical issues should be addressed in the design and planning of the clinical trials.<sup>16</sup>

### The researcher

In virtually all clinical trials in Nigeria, the researcher is also a clinician practicing in a tertiary institution. The researcher is also a University lecturer whose progression in the academic career is dependent on conduct of research and publications from such research. He/She sees participation in clinical trials as an opportunity to be involved in funded research. It provides an avenue to participate in high-quality research that could be published in high impact international journal. There is a prospect of international travel for meetings or sponsorship to international conferences. These are clear benefits of participating in clinical trials. On the other hand there are ethical challenges that the researcher faces.

1. He has to transform from his role as a clinician to his patient, to the role of a researcher to the research participant.
2. Capacity to conduct the research. Is the researcher competent both in academic qualification and experience to carry out the intended clinical trial? Is the researcher conversant with the basic ethical tenets in clinical trials and Good Clinical Practice (GCP)? Internationally, it is a requirement that researchers doing clinical trials must have taken a course in GCP and

Basic Research Ethics. There are several online courses on Basic Research Ethics and GCP, some of which are available at no cost.

3. In recruiting his patients as research participants how does he ensure that they voluntarily give their consent to participate in research? This is important against the background of the unequal power dynamics between the doctor and the patient.
4. How does he ensure that the patient fully understands that the activity he is being recruited into is research which has an uncertain outcome? In other words how does he ensure that 'therapeutic misconception' is avoided by the patient?
5. How does the Clinician/Researcher avoid the pressure of recruiting unqualified patients or vulnerable patients just to get the required sample size in order to receive the budgeted amount for patient recruitment?
6. In situations where the data from the clinical trial do not favour the test drug, would the researcher be able to resist any pressure from the study sponsor to manipulate data towards making the result favourable? In a survey of a group of researchers in Nigeria conducted by Okonta and Rossouw, 19.4% of the researchers admitted that they had succumbed to pressure from sponsors to alter data.<sup>17</sup>
7. Would the researcher succumb to the pressure of not publishing the results of the clinical trials if it does not favour the test drug - 'negative trials'? In an evaluation of studies on anti-depressants agents acting on Serotonin (SSRI), Melander *et al.*,<sup>18</sup> found out that of the 42 clinical trials registered only 25 were published. Of these 25 published, 19 documented positive results while only six documented negative results. Failure to publish negative trials systematically shifts any subsequent meta-analysis in favour of drug efficacy.
8. In publications and presentations of results of the clinical trials, it is mandatory for the researcher to declare the source of support/sponsors of the research and also any other conflict of interest that may be present.

These are examples of ethical challenges that face the researcher in the conduct of clinical trials and he has to overcome these challenges.

### The research participant — patient

Research participants in phases 2 and 3 of clinical trials are patients with the disease of interest. They have a clinical problem that made them present to the doctor. Their expectation is to be cured of their disease. In their consultation with the doctor, he/she informs them about a drug that is being tested for their illness and subsequently invites them to participate in the research. In Nigeria, the illiteracy level is comparatively high, it is difficult to explain to patients the concept of research, clinical trials and randomisation. It is difficult for them to imagine that there would be two tablets, similar in shape and colour,

but one would contain a drug and the other nothing. It is difficult for patients to believe that their 'doctor' would intentionally give them a tablet that contains nothing. They find it difficult to appreciate the doctor's role as a researcher. They believe that you already know that the drug would work — therapeutic misconception.

In clinical trials in developing countries, the amount for reimbursement for transportation and lost wages has been a source of intense debate. On one side of the divide is the call for a uniform amount to be paid to research participants in developed and developing countries involved in multicentre international trials. On the other side of the divide are those who argue that paying the same amount to participants in developing countries could constitute undue inducement that blind them from making an informed choice of participating in the trials. At the core of the ethical challenge affecting the research participant in clinical trials is the adequacy of the consenting process. How do you get a truly informed and voluntary consent from the patient without undue inducement or subtle coercion? Other ethical concerns that affect the research participants include

1. The standard of care. As started earlier, it is unethical for a Randomised Controlled Trial (RCT) to have an arm that offers treatment below the established accepted standard of care.
2. Ancillary treatment. Patients who have been recruited as participants in a drug trial should have access to ancillary care. This could be provided in the setting of the research health institution or an arrangement made to direct such patients to where it can be accessed. The extent to which research sponsors bear the burden of ancillary care is controversial; however, it is generally agreed that it is unethical to neglect a clinical condition in a patient that is although unrelated to the trial but was discovered during the course of the trial.
3. Compensation for injury associated with drug trials. Recruited participants in clinical trials should be insured against injury and offered compensation should injury occur associated with the trials.
4. Post- trial availability. This is very crucial especially in novel breakthrough drugs for life threatening or terminal conditions. The participant is concerned about the availability of the drug after the successful trial. Would the participant be denied access to a drug that has proven useful in the treatment of his disease? There is usually an interval between when a clinical trial of a successful drug has ended and when it becomes licensed and made available to the public. What happens to the research participants who require this drug for his wellbeing? What happens when the commercial price for the drug is unaffordable? Is it ethically right for a research participant to be denied access to a drug that he helped in generating the data that made it possible for licensing and subsequent production? The World Medical Association (WMA)

recently in October 2013 at her 64<sup>th</sup> General Assembly in Brazil revised the Declaration of Helsinki. Point number 34 of the declaration states:

'In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.'<sup>19</sup>

### **The Health Research Ethics Committee (HREC)**

The Health Research Ethics Committee (HREC) is the conscience of the research enterprise. It takes a holistic look into the ethical aspect of a clinical trial protocol while paying particular attention to the protection of the research participants. The National Code of Health Research Ethics in section E, subsection d (i) states that:

'HREC shall review prescribed application materials and have authority to approve, require modifications in (to secure approval) or disapprove all health research activities covered by this code.'<sup>20</sup>

All research involving human subjects (including clinical trials) must be approved by a HREC. In the Trovan study, it was established that the clinical trial protocol did not pass through ethical review process in Nigeria. Infact, there was no HREC in the health facility where the children were treated and the Kano State ministry of health had no HREC. It must be emphasised that clinical trial protocols must pass through ethical review and be approved in both the country of sponsorship and where the research would be conducted. Ethical approval from the country of sponsorship does not substitute for ethical approval from the country where the research will be conducted.

It is pertinent to acknowledge the efforts of the Nigerian government through the National Health Research Ethics Committee to promote ethical conduct of research in Nigeria. In the same vein, it is important to appreciate the assistance of the Government of the United States of America through the Fogarty Center of the National Institute for Health that has provided grants for training in research ethics to Nigeria and many developing countries.

It is expected that HREC would review a clinical protocol using several benchmarks.

### **BENCHMARKS FOR ETHICAL CONDUCT OF CLINICAL TRIALS**

Several documents have prescribed guidelines for ethical conduct of clinical trials and research in general. These documents include

1. Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects. World Medical Association, WMA.
2. The Ethics of Research Related to Health care in Developing Countries. Nuffield Council on Bioethics
3. International Ethical Guidelines for Biomedical Research involving Human subjects. Council for International Organization of Medical Sciences, CIOMS.
4. Standards and Operational Guidelines for Ethical Review of Health-Related Research with Human Participants. World Health Organization, WHO.

Most countries having adopted the ethical principles in these international documents have gone further to produce their own guidelines. The United States of America has the Code of Federal Regulations Title 45, Part 46 (45 CFR 46). In the United Kingdom, the Health Research Authority (HRA) of the National Health Service (NHS) has regulatory guidelines for various aspects of human research including clinical trials. In Nigeria, the National Health Research Ethics Committee (NHREC) has published the National Code of Health Research Ethics which contains benchmarks for ethical conduct of clinical trials and other research involving human participants.

5. What makes clinical research in developing countries ethical? The benchmarks of ethical research by Ezekiel Emanuel *et al.*<sup>21</sup>

These benchmarks are discussed below.

### Social or scientific value

The proposed clinical trial must have social or scientific value either to participants, the community or population they represent or the host country in order to justify the finite resources and risk exposure to some participants. In international collaborative research, the research should be integrated with comprehensive capacity building, technology transfer and health-care delivery strategies that address significant local health problems and add value to local participation of research. In a nutshell, the participants, researchers, host institution or even the country at large must have something to show for participating in the research. For example, a clinical trial that seeks to evaluate the efficacy of a test drug on a particular virus may require a PCR machine to assess viral load. If the host institution does not have a PCR machine, the proposed research should include acquisition of a PCR machine for the host institution in the research budget rather than collecting the samples to analyses abroad or elsewhere.

### Scientific validity

It is generally recognised that doing a study that lacks scientific validity is unethical. Therefore, for research to be ethical, it must have scientific validity. HREC should be competent to look into the scientific validity of a clinical

trial protocol being reviewed. Flaws in scientific validity could include:

- Lack of clear scientific objective(s);
- Use of invalid methodology;
- Underpowered study;
- Lack of equipoise in the clinical trial
- Lack of a plausible data analysis plan (including a specific role for a Data and Safety Monitoring Board [DSMB])
- Research with biased measurements of outcomes.

The ethical implication of doing a scientifically invalid research is that the time, resources, risk that patients underwent in the clinical trial will come to nothing since the results of the trial would be discredited based on lack of scientific validity.

### Fair selection of research participants

This must be done based on the objectives of the clinical trials. The recruitment of vulnerable groups such as incarcerated persons, persons in low socio-economic class, pregnant women and children, must be justified based on the objectives of the study and the inherent benefits accruable to them. Conversely such vulnerable groups should not be denied participation in research if they would benefit from it.

### Minimising risks and maximising benefits

The design of the clinical trial should be tailored towards the minimisation of risks/harm and maximisation of benefits. For example, use of non-invasive tests rather than an invasive test where both will give similar valid results.

### Clinical equipoise

There must be clear uncertainty of the efficacy of the test drug or the efficacy in a different population. It is unethical to continue to conduct clinical trials in a drug whose efficacy has been clearly established and there is no scientific reason to believe that available results cannot be generalised to other populations.

### Review of clinical trial protocol by HREC

All research involving human subjects must be reviewed by a competent ethics committee. In Nigeria, not all HREC are allowed by NHREC to review clinical trials. The list of registered HREC and their category is available at the NHREC website. Following approval of the clinical trial, the HREC should also monitor the conduct of the trials through regular progress reports and site visits. Ethical review and oversight assures society that reasonable attempts have been made to minimise the potential impacts of these conflicting interests and ensure balanced judgments.

### Informed consent

This is the cornerstone in the ethical conduct of research in general and clinical trials in particular. The NHREC has made recommendations on the contents of the informed

content document and process. The informed consent document should contain the following aspects:

1. Title of the research
2. Name(s) and affiliation(s) of researcher(s) of applicant(s)
3. Sponsor(s) of research
4. Purpose(s) of research
5. Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research.
6. Expected duration of research and of participant(s)' involvement.
7. Risk(s)
8. Costs to the participants, if any, of joining the research
9. Benefit(s)
10. Confidentiality
11. Voluntariness
12. Alternatives to participation
13. Incentive (inducement) to participants
14. Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation.
15. Modality of providing treatments and action(s) to be taken in case of injury or adverse event(s).
16. What happens to research participants and communities when the research is over?
17. Statement about sharing of benefits among researchers and whether this includes or exclude research participants.
18. Any apparent or potential conflict of interest.
19. Detailed contact information including contact address, telephone, fax, e-mail and any other contact information of researcher(s), institutional HREC and head of the institution.

It is important to emphasise that all consent process must be documented. In circumstances where participants are unable to provide signed consent, other alternatives such as thumb printing maybe done. Other alternative forms of documenting the informed consent process include witnessed audio recording.

### Respect for enrolled research participants

Research participants must be treated with respect at all times throughout the clinical trials. They must be reassured that their participation in the research although voluntary is highly valued and appreciated. All of their concerns about their participation in the research must be attending to and as much as reasonably feasible addressed.

### CONCLUSIONS

Conduct of clinical trial is the keystone in the development of new therapies for diseases. It is also at the centre of a multi-billion dollar enterprise having pharmaceutical companies, International NGOs, clinical researchers and human

research subjects as major stakeholders. Past experiences of unethical conduct of clinical trials especially in developing countries along with the increasing globalisation of research makes it imperative that all players should be aware of the ethical challenges in clinical trials and the benchmarks for ethical conduct of clinical research in Nigeria.

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