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CLINICAL TRIALS

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DEBATING MATTERS
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MOTION:

"CLINICAL TRIALS IN DEVELOPING COUNTRIES ARE EXPLOITATIVE"

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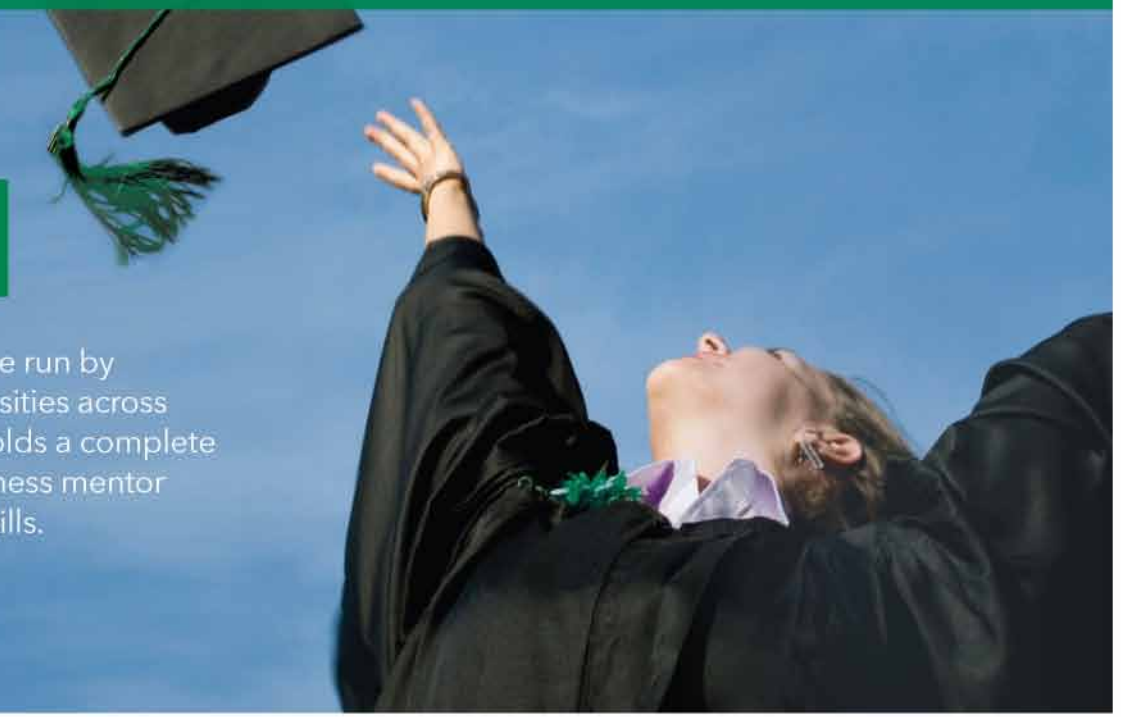

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CONTENTS

KEY TERMS

Capacity building

Clinical Trials

Clinical Trials Registry - India (CTRI)

Declaration of Helsinki (1964)

Ethics of clinical research

Informed consent

Medical ethics

INTRODUCTION

Until 1995, clinical trials were mainly conducted in the USA, Europe, and Japan, but in the era of globalisation drug companies have been steadily outsourcing their research enterprises to the developing world. According to an article in the New England Journal of Medicine, approximately one third of the trials conducted by the 20 largest US-based pharmaceutical companies now take place in other countries, 'many in developing countries' [Ref: NEJM]. Western research institutions also play a significant role in trialling drugs in the developing world, with particular emphasis on diseases such as HIV/AIDS, tuberculosis (TB) and malaria [Ref: Biomedcentral.com]. Some argue that the globalisation of clinical research brings global benefits, enabling pharmaceutical companies to test new drugs more quickly, effectively and cheaply [Ref: MedicalProgressToday.com] - the cost of conducting clinical trials in developing countries can be as much as 60% cheaper than in the West [Ref: TIME]. Commentators point to other advantages too; the existence of a large and genetically diverse population in India for example is said to provide a 'microcosm of the world' [Ref: Thaindian]. Clinical trials also bring resources and expertise to resource-poor countries, and give trial participants access to treatment that they would otherwise be denied. But others argue that 'Big Pharma' is exploiting the poverty of ill people in the developing world, by taking advantage of their need for medical help in order to make the maximum profit from new drugs. There is a concern that powerful companies and research institutions cannot be held to account by the poor, sick and frequently illiterate people who often become part of clinical trials, and that citizens of resource-poor countries are being used as guinea pigs for drugs [Ref: Wired].

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Are clinical trials in the developing world inherently exploitative?

Increasing global concern about unscrupulous trials has attracted adverse coverage in the media and medical journals. In recent years a number of high profile Public Interest Litigation (PIL) cases in India have even seen the Supreme Court intervene in this politically fraught area, demanding decisive action from government and the Medical Council of India [Ref: Business Standard]. In such scenarios, some argue that the outsourcing of clinical trials amounts to the outsourcing of risk [Ref: Guardian]. As people in developing countries often participate in clinical trials as their only way to access effective medical treatment, it is argued that trials take advantage of desperation, without providing the ongoing medical care that people need: for example, by ensuring that trial participants continue to receive medical care when the trial has finished. It is important to note that some clinical trials need to take place in the developing world – for example, if the effects of drugs designed to treat diseases such as malaria, which largely affect non-Western countries, are to be assessed. Additionally, as medical scientists become more aware of the impact of genetic differences on the way in which individuals respond to drugs, ensuring that tests are conducted on people with diverse genetic profiles becomes more important [Ref: BBC News].

Do clinical trials in resource-poor countries cause harm?

With all clinical trials, wherever they take place, there is some risk to the health of the participant. Some recent clinical trials in developing countries have been dogged by controversy over ethical procedures [Ref: SOMO]. In 2011 there were 438 deaths attributed to clinical trials in India. Cases such as the testing of the human papillovirus (HPV) vaccine on teenage girls in tribal regions of Northern India, a study which involved 23,000 girls, 6 of whom died, have raised further questions about the ethical framework under which such trials are operating, despite a scientific investigation finding that the deaths weren't linked to the vaccine [Ref: Nature]. But, some argue, while it is possible for trials to be poorly designed, this is different from arguing that outsourcing clinical trials is itself a problem. The potential for harm needs to be balanced against the potential benefits afforded by new drugs, both for the trial participants and for human health in general [Ref: The Times]. Some speak very positively about the benefits of clinical trials, wherever they are undertaken and furthermore, suggest that India and other countries have a unique opportunity to train themselves in drug development, and to play a part in global medical progress [Ref: Hindu].

How are concerns around regulation being addressed?

The broad principles governing clinical trials were laid out in the 1964 Declaration of Helsinki [Ref: BMJ], which has been revised several times [Ref: WMO]. Two key principles for regulating clinical trials are that the participants must give their informed consent to take part and that the study should be approved by an ethical review committee Few would deny that both the pharmaceutical industry and research institutions have taken steps to establish stronger procedures to secure informed consent and greater ethical oversight [Ref: The Ethox Centre].

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However, critics of clinical trials in developing countries point out that the vulnerability caused by poverty and illiteracy make it difficult to ensure that participants fully understand the risks and consequences of trials, and generate substantial obstacles to achieving appropriate levels of regulatory checks and ethical oversight [Ref: NEJM]. Another perspective is that adherence to a 'one size fits all' ethical standard can amount to a paper approval which distracts researchers from taking on board their own responsibilities for developing an ethical approach that is appropriate to the context in which they are working [Ref: American Scientist]. Are international regulations enough to ensure decent treatment of trial participants? To what extent can national regulations in resource-poor countries protect their citizens' interests in relation to clinical trials [Ref: IJME]? And is there a danger of over- regulation?

Who benefits?

Conducted appropriately, clinical trials themselves can provide several benefits. The participating physicians get first-hand experience of new drugs as well as extensive training. Resource-starved public hospitals see trials as a source of funds for much-needed improvements in infrastructure, and it is argued that those with diseases benefit since they get free, focused and more frequent medical supervision for the duration of the trial. New drugs and treatments can be trialled that are of direct importance to the health of people in participating countries, whilst involvement in international trials is beneficial for the science base and, in some places such as India and South Africa, the economy of the country involved. Once predicted to be the new global centre of clinical research, a recent decline in the number of trials now undertaken in India has encouraged commentators to make the case for their economic benefits – especially as it has been reported that the proportion of global trials currently being conducted in China is significantly higher than in India [Ref: Mint]. Furthermore, advocates argue that much has been done to improve ethics procedures in developing countries and that exploitation of people can be avoided through strategies that emphasise capacity building and through developing appropriate forms of ethical regulation [Ref: Nuffield Bioethics]. The lower costs of trials in these countries also allow trials to go ahead which would be unfeasible otherwise. Others argue that a clinical trial, which provides resources for a limited time that may disappear after the trial is over, takes advantage of the gap left by a decent healthcare infrastructure. There also exists a wider cultural context of unease about the motivations, actions and accountability of the global pharmaceutical industry [Ref: Nation]. Can an appropriate balance be struck between the demands of Western pharmaceutical companies and research institutions and the needs of trial participants?

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NOTES

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ORGANISATIONS

African Malaria Network Trust

Bionet

European-Developing Countries Clinical Trials Programme (EDCTP)

Indian Council of Medical Research

International Federation of Pharmaceutical Manufacturers and Associations

Medical Research Council

SOMO

The Council for International Organizations of Medical Sciences (CIOMS)

Wellcome Trust

World Health Organisation

World Medical Association

NOTES

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