MOTION:

“CLINICAL TRIALS IN DEVELOPING COUNTRIES ARE EXPLOITATIVE”
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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].
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].
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: JME]? 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?
**ESSENTIAL READING**

**FOR**
- The dark underbelly of India’s clinical trials business
  *Mint* 10 October 2012
- Clinical trials in India a delicate line to tread
  *Pillman DNA India* 5 January 2012
- Without consent: how clinical drugs companies exploit Indian ‘guinea pigs’
  *Andrew Buscombe Independent* 14 November 2011
- Unregulated Clinical Trials, Exploitation, and Profit: How the FDA Allows Big Pharma to Exploit
  *Kelly Hearns Nation* 28 September 2011
- The Other Half: Too bitter a pill
  *Sharma Kalpana Hindu* 12 June 2011
- The ethical minefield of drug trials
  *Anne Perkins Guardian* 24 September 2009

**AGAINST**
- No reason to fear clinical trials
  *M D Nair Hindu* 1 August 2012
- Clinical Trials Have Gone Global: Is This a Good Thing?
  *Trudie Lang and Sisira Siribaddana PLOS medicine* 12 June 2012
- Don’t be averse to clinical trials, fix the system
  *Seema Singh Forbes India* 9 May 2012
- Burkina Faso welcomes drugs trials
  *Tatum Anderson Guardian* 10 December 2009
- South Africa Today: Economical development and regulatory standards make the country trials choice
  *Karen Politis Virk Applied Clinical Trials* 1 November 2009
- Outsourcing on trial: Why outsourcing clinical trials to poor nations will improve global health
  *Philip Stevens Medical Progress Today* 8 June 2006

**IN DEPTH**
- Ethical Riddles in HIV research
  *TEDx January 2013*
- How the FDA Stifles New Cures, Part I: The Rising Cost of Clinical Trials
  *Forbes* 24 April 2012
- Stronger code of practice for Global Pharma Industry
  *Ben Stovall Health Blog Wall Street Journal* 1 March 2012
BACKGROUNDERS

Africa blamed for tolerating unethical clinical trials
Ntaryike Divine Jr World Federation of Science Journalists News
12 July 2011

Vaccine trial’s ethics criticized

Help, Harm and Human Subjects
Sheldon Krimsky American Scientist January 2010

Should Clinical Trials Be Outsourced?
Madhur Singh TIME 7 August 2008

Scientists on a mission to bring cheap drugs to the world’s poorest countries
Sarah Boseley Guardian 2 January 2007

How the world’s drug firms sacrificed profits in the battle against Aids
Karen Attwood Independent 1 December 2006

Colonialism of clinical trials: discerning the positive spin offs
Bashir Mamdani, Meenal Mamdani Ind Mamdani Indian Journal of Medical Ethics Vol II No. 4 October 2005

A new colonialism? — Conducting clinical trials in India

Nuffield Council on Bioethics: The ethics of clinical research in developing countries
October 1999

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
IN THE NEWS

Indian Supreme Court’s anger over unregulated clinical trials
chemistryworld 25 January 2013

Concern at outsourced clinical trials in developing world
BBC News 28 November 2012

Government tightening clinical trial norms
Business Standard 6 August 2012

PATH’s claim of India’s large burden of cervical cancer faulty: study
Hindu 26 July 2012

Phase III trial of dapivirine ring begins in Africa: New HIV prevention approach for women
Science Codex 25 July 2012

Landmark Alzheimer’s Prevention study
ThirdAge.com 24 July 2012

Three-in-one drug wipes the floor with TB
New Scientist 23 July 2012

Developing countries up to scratch in trial data
Pharma Times 17 July 2012

SC slams Centre for human drug trials
Indian Express 16 July 2012

Policy simmer puts clinical trials on a slow burner
Hindu 14 July 2012

Clinical trials get bad press for nothing: Experts
Deccan Herald 13 July 2012

India accounts for 1.5% of global drug trials on humans
Asian Age 8 July 2012

World’s first malaria vaccine works in major trial
Reuters 19 October 2011

UK clinical trials in dramatic decline, NHD confederation says
Pharma Times 9 June 2011

Clinical trial deaths and compensation in India
Pharmalot 5 May 2011

Karnataka denies ban on clinical drug trials
Sify 4 May 2011

Clinical trials: US, China ahead
Times of India 5 February 2011

Concern over foreign trials for drugs sold in US
New York Times 21 June 2010

Trial HIV vaccine leaves 46 infected
Daily Nation 12 January 2010

Fall in clinical trials of drugs
Financial Times 31 December 2009

Are health and safety rules slowing medical progress?
Guardian 21 October 2009

India a preferred destination for clinical trials: study
Hindu 10 August 2009

Bill to regulate human genetic research soon
Business Standard 31 July 2009

Should Clinical Trials Be Outsourced?
Madhur Singh TIME 7 August 2008
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