

## **The Ethics of Clinical Trials in India: An Indian Perspective**

**By Ketan Desai**

The developed world has a responsibility for ethical conduct in the developing world. However, it can easily stray into making paternalistic decisions that do not respect the ability of competent people in the developing world to make decisions for themselves. In particular, it is unrealistic to expect a clinical research professional in suburban Philadelphia to understand the social, cultural and economic environment in a city such as Mumbai, India. As the clinical research industry expands in developing countries such as India, it faces important ethical questions, such as:

### **Is it legitimate to conduct studies in a country with an immature regulatory and oversight environment?**

India's clinical research regulatory processes are somewhat ill-defined. The office of the Drug Controller General of India (DCGI) is severely understaffed. Ethics committees are few in number and relatively inexperienced. As a consequence, some Indian and even multinational drug companies have conducted trials that would not have been approved in the U.S. However, as multinational companies expand their clinical research activities in India under ICH Good Clinical Practices (GCP) and FDA inspections, the regulatory and oversight environment will quickly mature. Ethics committees in India will benefit from interactions with their U.S. counterparts. Economic interests will encourage India's regulatory authorities to clarify the rules, expand their resources, and improve skill levels. While drug companies currently carry too much of the ethical burden, this imbalance will resolve over time. Therefore, it is not only legitimate to conduct trials in India, but beneficial for India's growth in regulatory and oversight capabilities.

### **Does it benefit India to distract physicians with clinical research when they are needed for regular medical care?**

There is no shortage of physicians in the urban areas of India, where clinical trials are conducted. Urban physicians are trained in Western medical methods, but as treatment providers and not scientists. For such physicians, taking part in clinical trials is very beneficial since the process of conducting clinical trials encourages scientific thinking. Participating in clinical trials also gives physicians a chance to be on the cutting edge of new technologies and scientific developments that open their eyes to medical innovation. It may even lead them to create biopharma companies that address the needs of the developing world.

The economic opportunities created by clinical research draw more talented people into the medical profession. Clinical research creates employment for site personnel, study monitors, and ancillary services, with an economic impact on the whole community. India's workforce exceeds 480 million and is rapidly expanding, so every new job is important.<sup>1</sup>

### **Is it fair to test experimental drugs on poor, illiterate people in a country where the drugs are unlikely to be marketed or affordable for many years, if ever?**

Some might argue that patients are exploited when they are asked to participate in trials for medications they cannot afford. The counter-arguments, however, are numerous:

- As a physician, I would be happy to have my patients benefit for even a short time than not at all.
- India is a free country. Doctors do not force their patients to participate in clinical trials. Generally speaking, Indians are similar to Americans in being highly individualistic. It is not easy to coerce them into taking part in something they do not believe in.
- Inviting poor patients to participate in clinical trials inherently gives them access to medical care they could not otherwise afford. The potential for undue influence thus rears its ugly head. However, it is discriminatory to block participation on the basis of educational status or poverty. Pharmaceutical companies invite poor U.S. citizens to participate in clinical trials every day, without any ethical malfeasance. Adjusted for purchasing power, subject stipends in India are about the same as in the U.S.
- About 560 million Indians – almost twice the entire population of the U.S. – are literate.<sup>1</sup>
- It is clearly unethical to conduct a clinical trial in India that ethically cannot be conducted in the U.S. However, most clinical trials in India are usually part of larger multinational trials.
- Trials for developing-world diseases such as malaria must be conducted in developing-world countries. However, as India makes the transition to the developed world, “rich people” ailments such as diabetes, cancer and heart disease are becoming rampant.<sup>2</sup> Many people in India need new medications for these conditions now, and many more will need them in the future.
- Just as Indian companies are free to conduct studies in the U.S., U.S. companies should be free to conduct studies in India, so long as they follow the rules.
- New drugs may be exorbitantly expensive, but patents eventually expire and medications become much more affordable. For developing countries, it’s better late than never.
- U.S. patients will eventually refuse to unilaterally fund global pharmaceutical research and development. The cost of medications all over the world will then rise. By participating in low-cost clinical trials, Indian patients can help keep the cost of new drugs low for everyone.

## Conclusion

Conducting clinical trials in India is a win-win situation for everyone. Pharmaceutical companies win by reducing costs and timelines. India wins by increasing physician training, improving regulatory and oversight standards, providing job opportunities, and helping patients individually and collectively. Patients benefit by obtaining access to new drugs and a more scientific medical profession. That there are potential pitfalls cannot be denied, as is true for any endeavor. Our role as clinical research professionals is to navigate through those pitfalls for everyone’s benefit.

## References

1. “The World Factbook”, CIA, last accessed on 11/28/05 at <http://www.odci.gov/cia/publications/factbook/geos/in.html#People>.
2. National Human Development Report: 2001, Planning Commission of India; last accessed on 11/28/05 at <http://planningcommission.nic.in/reports/genrep/nhdrep/nhdreportf.htm>

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