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Clinical trials, a lost opportunity for India

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Around the world, in both developed and emerging economies, clinical trials are testing new and promising drugs to treat cancer, diabetes, TB, HIV and other serious conditions. However, in India, only a handful of new clinical trials of major experimental drugs have been initiated on patients, either using public or private industry funds, since early 2013. This is a worrying statistic for a country comprising one-seventh of the world's population. The current state of affairs needs to be addressed in order to prevent a humanitarian, public health and economic development disaster.

In the medical sphere, India represents both a developing and a developed country, with a large part of the population served by overburdened, poorly-equipped public clinics and others (mostly the upper middle class and the wealthy) seeking care at private medical centres whose expertise and equipment rival those of the best hospitals in the US. The socio-economic transformation that the country has seen in the past decade has led to a surge in the incidence of lifestyle disorders, while the traditional diseases of a developing economy persist. Because of its huge population and serious health problems—diabetes, TB, HIV, malaria, cardiovascular diseases, among others—and because it has a significant cohort of physicians who are experienced in conducting clinical trials, India was, until early 2013, a favoured destination for industry and medical academics who were seeking locations for clinical trials. The clinical trial industry in India was robust, with a number of high-tech industries such as clinical research organisations and data processing firms—many of them India-based and India-owned—springing up to service the research enterprise. Until these recent regulatory changes, clinical trials had been offering new hope to patients and represented opportunities for medical, scientific and social advancement for the country. In 2012, an Indian NGO filed a lawsuit against the Indian government, alleging that thousands of Indians had been injured or had died while enrolled in clinical trials in India, with inadequate informed consent, and that the Indian government's regulatory framework for approving and regulating clinical trials was inadequate.

The lawsuit's allegations were, unfortunately, partially correct, in that the Indian drug safety agency has been historically underfunded and inadequate to its tasks. But the lawsuit appeared to have ignored the fact that just because an injury or death occurs during a clinical trial does not mean that the injury or death was caused by participation in the trial. For example, end-stage cancer patients may die while enrolled in a trial but that is often due to the natural history of their disease. And people get hurt and killed in traffic accidents while enrolled in trials but that is hardly due to the trials.

The government's response to this and other criticisms from Indian scientists and clinicians was to issue some confusing amendments and a new requirement that all informed consent conversations with all participants must be audio-visually recorded, even when the participants prefer (as many in India do, due to cultural and religious preferences for personal and family privacy) that they not be recorded. Other studies—as in a treatment, vaccine or public health study that is low risk and that addresses a major Indian health problem—need to enrol thousands of participants, but a requirement that all participants' informed consent be videotaped imposes a transaction cost, so crushing the hope that such studies just won't be done in the future in India. The Indian Parliament has also weighed in, proposing criminal laws with jail time for physicians who don't strictly follow research protocols. The unintended

consequence of all this has been chaos and disruption in clinical science and public health research in India.

Most major pharmaceutical companies, every American medical institution, many leading Indian medical institutions, and the National Institutes of Health (NIH) have elected to forego starting or funding major new drug and medical device trials in India. This deprives Indian patients of access to experimental treatments. More importantly, since Indian drug approval regulations require that some studies of new drugs be conducted and completed in India before a new drug can be approved for sale in India, this means new approved drugs also cannot be made available to Indian patients.

With few new major drug trials initiated in India since early 2013, new drugs now being tested and soon to be approved all over the world will not be available to the people of India (because without Indian trials they cannot be approved for use by Indians). Undoubtedly, the wealthiest will get treatment in London and Singapore, but the vast middle and lower classes in India will be deprived of all access to new drugs even after they have been approved by the FDA, the European Medicines Agency and other national authorities. This is a public health and humanitarian disaster unfolding in slow motion.

In collaborative efforts with Indian colleagues—many of whom have made their own cogent suggestions for remedies—we have tried to advise the government to retract and refine these regulations and adopt other approaches that have been successfully employed in other countries. Without doubt, there is an ethical imperative that people who are injured directly because of participating in trials, whose injuries are caused by the test drug, should be compensated and medically managed, but the Indian regulatory framework, as it stands today, does not effectively address these problems. Instead, the current regulations are over-broad and imprecise, and have done more harm than good. The actions of the Indian government to date have impaired the future access of the entire Indian population to new and promising drugs. We hope the new government will take note of, and remedy in short order, the policy excesses of its predecessor.

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