



Combating Corruption and Unethical Behavior in Clinical Drug Trials in Kerala, India

CSO:	JANANEETHI
Years:	2009 - 2010
Country:	Kerala, India
Amount:	\$17,000 USD
Sector:	Controlling Corruption in Delivery of Social Services: Health

Corruption Problem:	Human Rights violations and public health impediments in unregulated clinical drug trials
Tools employed:	Advocacy, RTI, Survey, Capacity Building, Awareness Raising, Investigation, Media

Inadequate rules and regulations and poor or no government enforcement of these rules within the sector of clinical drug trials in Kerala State, India, have led a local CSO, JANANEETHI, to start investigating the field and research structural flaws that violate human rights and result in poor delivery of public health services. Through its actions, JANANEETHI has successfully engaged authorities to take up the issue and create awareness among stakeholders. Closing loopholes, eliciting an ethics debate and prompting government agencies to enforce and oversee drug trials have rendered JANANEETHI’s intervention highly successful. A second phase of the project is under way.

Corruption Problem Addressed

India has become a global hub for clinical drug trials on human subjects, reportedly worth \$400 million USD and growing by over 30% per year. Until the 1990s, most clinical research was carried out in academic medical centers and financed by the Government. Recently, commercial interests have started dominating the drug trial scene in which the financial bottom-line can override ethical and human rights concerns. A number of factors are responsible for the current increase in drug trials conducted in India. These include the low

cost of experiments, almost 60% less than comparable trials in Europe or the US, and access to a large pool of illiterate and relatively less educated patients with a wide variety of diseases. Trials became easier after the 2005 amendment of the Drugs and Cosmetics Act of 1940 permitting concurrent trials. These factors and the absence of specific laws to protect patients have led to widespread corruption in clinical drug trials.

Rampant corruption has been alleged from the highest policy level down to local institutions. The regulatory mechanism is steered from the drug controller’s office at the center with little involvement and control at the local levels. Bioequivalence trials offer participants large payments in violation of existing ethical guidelines inducing poor people to risk their lives. At present, sound and ethical clinical trials depends mostly on personal integrity and honesty of the investigator concerned. While corruption is so widespread, there are no specific laws to prosecute illegal or unethical activities.

Actions Taken by JANANEETHI

During the first phase of the project, JANANEETHI focused on identifying the problems in drug trials and the underlying structural weaknesses in the regulatory system. It identified five participants of

drug trials and recorded their experience. In continuation, the CSO identified the weaknesses in the regulatory mechanism through personal interviews conducted with members of a variety of institutions, including medical colleges; ethics review boards, hospitals, staff and doctors responsible for the trials and others working on ethical standards of drug trials. The research exposed serious shortcomings and loopholes.

JANANEETHI felt that the Government of India had aggressively encouraged foreign drug trials without establishing necessary protective measures and without guaranteeing inadequate effective regulatory mechanisms. JANANEETHI also felt that the Central Drugs Standard Control Organization (CDSCO), the principal regulatory agency, lacked capacity and/or the will to carry out its functions including the scientific review of trial protocols and monitoring the conduct of trials. Ethics committees were not adequately equipped or trained nor were they held accountable for their decisions. The confidentiality clause in the Indian Council for Medical Research (ICMR) guidelines indemnified the researchers who violated ethical norms and good practices while not protecting the privacy of trial participants. Physicians received huge incentives and payments to recruit trial subjects. Often patients would not know they were being used as test cases. Simultaneously, necessary medical treatments and compensations were denied or withheld for a growing number of trial related injuries and deaths occurring among the test population.

JANANEETHI has published a handbook on ethical standards of clinical trials for capacity-building purposes and undertook awareness raising activities with the full range of stakeholders involved, including briefing media representatives aiming to launch a state wide campaign on appropriate practices and ethical standards for

drug trials reaching out to the public through radio programs, television and other media.



Awareness raising workshop at Crescent College of Nursing, Pkd

The CSO also reinforced existent outreach to medical professionals and members of various ethics committees, awareness raising classes for medical students and other affected parties. Project activities furthermore included: advocacy through presentations to government officials, Members of Parliament, the State Legislative Assembly and heads of medical institutions; select monitoring of drug trial activities; and coalition building among concerned institutions.

All these activities will be reinforced and strengthened in a follow-up to the first project phase to ensure sustainable results and make use of the successfully created momentum.

Impact and Results Achieved

JANANEETHI has successfully carried out an extensive investigation and has brought to surface the serious shortcomings, malpractices and violations of guidelines in the fast growing business of clinical drug trials in India. Its research has also shown that while there were a few guidelines, no



specific law existed to enforce them and punish violators.

JANANEETHI has been highly successful in elevating the issue of corruption in drug trials to the national level. As a result, JANANEETHI was contacted and has submitted a report to the Human Rights Commission which is investigating rights violations in drug trials. JANANEETHI also participated in the first ever national consultation on the regulation of clinical trials which was held in collaboration with representatives from ICMR, World Health Organization, CDSCO, international medical research organizations and members of a Parliamentary Committee. While there was initial resistance on behalf of the authorities at first, constant pursuance and endurance on behalf of JANANEETHI has prompted officials as well as doctors and other stakeholders to constructively engage with the project and start furthering its objectives of realizing safe and ethical drug-testing.

JANANEETHI has succeeded as a whistleblower in Kerala, publicly challenging and protesting corrupt practices in drug trials. JANANEETHI was promised by the Health Secretary of Kerala that strict measures would be taken to respect ethical practices in drug trials. The second phase is expected to create further results in awareness building through campaigning for sound ethical practices under international accepted norms in clinical drug trials.

Documentation

Project completion reports and project completion assessments can be accessed at the PTF website www.ptfund.org under the “Where-we-work” section

See www.jananeethi.org for drug trial project news and reports

Further information can be found at: www.icmr.nic.in regarding clinical drug trial guidelines in India; www.ctri.nic.in for details of ongoing drug trials in India; www.cser.in for publications, studies and reports on various concerns regarding clinical drug trials in India

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