

## Ethical standards of Indian clinical trials are not getting diluted

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India is a growing centre for clinical trials and according to report, India now participates in over 7% of all global Phase III and 3.2% of all global Phase II trials. Further, India is set to grab clinical trials business valued at approximately US\$ 1 billion by 2010, making the subcontinent one of the world's preferred destinations for clinical trials. While good news for India's economy, the booming clinical trial industry is raising concerns because of a lack of regulation of private trials and the uneven application of requirements for informed consent and proper ethics review. I strongly feel India is filling the loopholes and striving to expertise the clinical research. Steps are taken to overcome these concerns.

- India has strong Ethics guidelines for clinical research and every clinical trial program should be reviewed by an ethics committee
- Indian biomedical research ethics guidelines available at: ICMR Ethical Guidelines for Biomedical Research and CDSCO has also set up Regulatory guidelines especially in relation to financial compensation for trial related injuries
- Registration of clinical research projects to enhance transparency
- Expanded roles of EC - Monitoring of clinical trials; Overview of consent process and decide on compensation to trial participants.
- Aids for illiterate – I was involved in the development of speaking book in local language
- Illustrations, descriptive consent forms
- Training of Investigators and Ethics committee members on GCP
- I would like to end by stating examples of clinical trial death reported in media which were Myth than Facts.

### Biography

Pingali Usharani has completed MD in pharmacology and later DNB in Clinical Pharmacology in 1993. Joined as faculty in NIMS, superspeciality hospital in 1996. Presently working as Additional Professor. Trained in GCP and Bioethics. Published about 80 clinical research papers in national and international journals. Edited a book in Clinical research and contributed about 36 chapters in text books. Editorial Board Member of Indian Journal of Pharmacology. Presented more than 50 papers in scientific meetings and delivered guest lectures on Clinical research topics in national and international meetings. Teacher and guide to DM Clinical Pharmacology and PhD students.

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