Appendix – VII

Clinical trials

Clinical trials usually employ Good Clinical Practice (GCP) guidelines developed by the International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the principles contained in the Declaration of Helsinki on the "Ethical Principles for Medical Research Involving Human Subjects" (2004). Clinical Trials also use Good Laboratory Practice (GLP) guidelines for bioequivalence research. The ICH guidelines also provide internationally accepted ethical and scientific quality, standards for designing, conducting, recording and reporting trials. Besides, they also cover issues such as selecting and training trial investigators, gaining informed consent from trial participants and monitoring and quality assurance aspects. While the GCP has already been incorporated in Schedule Y of the Drugs and Cosmetics Act, 1940, more needs to be done by way of implementation of the same.

Several threats face this 'sunrise' sector. The growth of foreign competition has been rapid and the evolution of Indian quality standards has been slow. Sufficiently qualified personnel have also been difficult to come by. One major difficulty that this industry has faced in the past has been the uncertainty with regard to regulatory approval, due to the Drug Controller's reliance upon external experts from institutions such as the IMRC. The IMRC's *Ethical Guidelines for Biomedical Research on Human Subjects* was evolved in 2000 whereas; the Indian Good Clinical Practices only became available in 2001.[25]

The United States has mandated that all clinical trials reviewed and approved by the Food and Drug Administration (FDA) must be reviewed and approved by an Institutional Review Boards (IRB). IRBs, Independent Ethics Committees (IEC), or Ethics Review Boards (ERB) are formal groups of professionals designated to review and monitor research involving human subjects. India, in order to successfully undertake clinical trials needs to employ a greater number of proficient Institutional Review Boards, which have professional competence in addition to their knowledge of international and national regulations, applicable laws and standards of professional conduct and practice.

Clinical Trials are tied in (though not always) to the process of R & D and in R & D India faces stiff competition from China, Russia and the United States, since R&D often gravitates to countries with large domestic markets for the resulting products.[26] India will continue to have a significant advantage over the next few years, due to its proficiency in back office work, etc.[27]

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[25] Cygnus, "Contract Research and Manufacturing Services in India", May 2006, p.55.
[26] Diana Farrell, Noshir Kaka, and Sascha Starze, "Ensuring India's Off-shoring Future", 2005 Special Edition, *McKinsey Quarterly*, available at **www.mckinsey.com**.
[27] *Id.*

While some fiscal incentives already exist, such as the waiver of customs duty for import of clinical trial samples and income tax benefits, specific state level incentives need to be given with regard to land and schemes for the setting up of these institutions.

A single window for regulatory clearance could be created which operates within a fixed time frame, allowing for the delivery of results within tight deadlines.

Research Design: Research design is one of the factors determining success in clinical trials. Indian firms while designing their clinical trials need to place greater emphasis on simple and highly informative schedules in the design, information about the subject, clinical data of the subject, disease parameters and planning. The number of subjects in each stage, detailed procedures for conducting and analyzing the data also need to be explained properly.

Infrastructure: To carry out clinical trials successfully, Indian firms need to scale up their infrastructure facilities such as hospitals with modern imaging technologies, facilities like ECG, Biochemistry Laboratory, X-ray Units, CT and MRI and round-the-clock availability of specialists.

Data management: Clinical trial data management is of prime importance in the selection of subjects, accuracy of subject recruitment rates and for obtaining real estimates of diseases of global interest. Leveraging the country's strong IT base, companies, institutions and Contract Research Organisations (CROs) involved in clinical trials should expand their data management segments creating infrastructure that can integrate huge amounts of data from genomics, proteomics and healthcare facilitating critical conversion of data into drug discovery and new treatments, thereby, cutting costs and shortening the development cycle.

The incentives mentioned in the draft National Pharmaceuticals Policy of 2006 such as exemption of service tax for direct investment in the field of clinical development and data management, exemption from import duty, improved regulatory infrastructure and some form of protection for undisclosed test data etc., ought to be acted upon.

Currently, India is experiencing a growing number of collaborations between Indian and foreign firms in the domestic market, especially involving the biotechnology sector, in a wide variety of areas such as collaborative R&D (including drug discovery and clinical trials), co-marketing and manufacturing.

India and China's drug outsourcing discovery markets combined are currently worth around $7.3 billion and driven by government initiatives to diversify the drug discovery portfolio and develop infrastructure, are set to reach $19.8 billion in 2011, say analysts at Frost & Sullivan.

There are dozen GLP approved research laboratories in India having several facilities. The total number of different facilities available with these labs is tabulated in the Table 27 below.

Table 30: GLP Approved facilities in India

Facility Type	No. of facilities
Toxicity studies	11
Mutagenicity studies	9
Analytical and clinical chemistry testing	8
Physical-chemical testing	7
Environmental toxicity studies on aquatic & terrestrial organisms	4
Residue studies	3
Studies on behaviour in water, soil and air; bioaccumulation	2
Studies on effects on mesocosms and natural ecosystems	1
Studies on natural enemies and predators	1
Safety Pharmacology and Pharmacokinetic Studies	1
Others (drug metabolism & pharmacokinetics [DMPK] and tissue distribution studies)	1