Name *Ms. Banusri. S*
Department *PhD in Law*
Ref. No. *COE/PhD/Law/18/2011*
Supervisor *Professor V.K. Gupta*
Faculty Of Law, JMI
Co-Supervisor *Professor S.K. Gupta*
ICR(I), Delhi

Comparative Analysis of the Legal Framework Governing Clinical Trials in India and United Kingdom

Abstract

Aim: A comparative study was conducted on the Legal Framework Governing Clinical Trials between India and United Kingdom (UK).

Methodology: Relevant statutes were collected from both the Indian and the United Kingdom jurisdiction and then their salient features were compared and contrasted with regard to origin, responsibility of various stake holders, approval mechanism, documentation, record keeping, informed consent, human subject protection requirements, detection & redressal of fraud, misconduct, other violations, the litigation and legal principles of Clinical Trial (CT) This study was further extended to conduct two questionnaire based surveys to assess the legal knowledge and perception of general population about their participation in clinical trials and legal knowledge and perception of Clincial Trialist (CTr) in India.

Results: Despite India having ancient medical ethics literature, UK pre-dates India in having specific clinical trial regulations. Indian clinical trial regulations came in response to intellectual property and marketing demands unlike the UK where the regulation had it continues presence along with the research initiatives of health care professionals and Pharmaceutical drug research. Unlike UK, the main provisions in Indian statutory framework are limited and GCP guidelines are referred to by way of inclusion for detailed roles and responsibilities without any statutory back up. Unlike India, CT regulatory frame work of UK specifies the CT offences and prescribes penalties for the same. The integrated research application system and common technical documentation of UK could be a preferred model as a one stop approval for India while dealing with various

regulatory & approval authorities and many streams of medicine. The public awareness survey revealed that majority of the Indian public lack awareness regarding CT regulations. Clinical Trialists' survey in India revealed that the doctors who conduct CT confuse aspects of treatment with research. This survey has also observed use of exculpatory language in the informed consent and lack of initiation to read the relevant statutes among Indian CTrs. Both the surveys favored a specific redressal provision for clinical trial violations instead of conventional mechanisms.

Conclusion: Indian statutory frame work that governs Clinical Trial is inadequate and ineffective in regulating certain essential aspects of clinical trial practices and requires prompt legislative intervention.

Key words: Health Law, India, UK, Clinical Trial, Clinical Trialists, public awareness, Legal Framework, regulatory framework, Comparative Law, survey.

Brief Profile of the PhD Scholar:

After my Higher Secondary School education from Tamilnadu (1992), I got admission in the premier Medical Institute, All India Institute of Medical Sciences at New Delhi. I pursued my BSc (Hons) in Nursing from AIIMS (1996) and this made 'Public Health' as an inevitable element in my life and career. The interest in consumer justice and health law prompted me to study Law. I pursued my LLB from Delhi University (2000).I started my advocacy practice after my Bar Council registration in 2001. I took the branch "Contracts including Mercantile law" for my Post graduation in law (ML-2006) from Annamalai University, Tamil Nadu. I was fortunate to get admission in Faculty of Law, Jamia Millia Islamia in 2007 to pursue my PhD in Law on the thesis entitled, "Comparative Analysis of the Legal Framework Governing clinical trials in India and UK", under the guidance of Prof. V. K. Gupta, Faculty of Law, Jamia Millia Islamia and Prof. S. K. Gupta, Institute of Clinical Research.

Address for communication:

Ms. Banusri.S
No.E-17, Type IV Qrts
Ayur Vigyan Nagar, New Delhi-49
Phone: + 91-11-26261439 (Home)
+ 91-9810996672 (Mobile)
Email: banusriv@gmail.com