



Mr. S.V. Krishna Prasad

CEO & Director, Cito Healthcare (P) Ltd., India

Clinical Trials – Testing in Humans projected as exploitation- how much is perceptive and how much is reality? – Specific to India

Well, the regulatory approval process especially at the DCGI office has slowed down a bit. As recent as last fortnight there was a new official who has occupied the chair and with his background in IPC (Indian Pharmacopeia), it is hoped that we would have a better understanding professional who knows the importance of bioscience, the clinical trials as pathway to the drug development process yielding the benefits of affordable drugs to the common man. The stringent systems that are being put in place are for the good of the industry. The black sheep or the bad apples get eliminated and the survival of the compliant is the name of the game. Not for nothing India is the most audited site by the USFDA next only to the US; this goes to prove that India has the potential to have the clinical research industry flourish as part of global multi-country studies.

Ethics committees are also being trained on their role and responsibilities, including their composition. One of the main objectives is to spread awareness and build a culture of ethics in clinical research earning trust from all stakeholders. As per the revised Schedule Y, apart from the ethics committees writing their own SOPs, steps are being taken to ensure these committees inspect the study for each protocol that gets approved by them. Volunteer consents to be obtained well before the check-in etc. The days are not far when each of the IEC/IRBs need to be accredited by a governing body either directly by the respective governments or through the now active ACRO.

Clinical Trials Registry of India and the DCGI mandates that all studies need to be registered on this site is a step in this direction. The Feb 2012 indication is that BA/BEs too require registering. However, this is yet to be implemented.

Quality training institutes in clinical research such as the Academy of Clinical Excellence (ACE) Bombay College of Pharmacy in Kalina The Indian Society of Clinical Research (ISCR) is another effort. Setting up of the Independent Ethics Committee (IEC) is another good possibility in each of the major cities). Frequent interaction by panel discussion among the regulators and representatives from media, patients, NGOs, sponsors, investigators, and ethics committees could dispel the myths surrounding the reality that is clinical research in India.

Against this backdrop, do we still believe that serious work is not going on in the world of clinical research as is happening in India? For a multi-national bio-pharmaceutical company, corporate image and trust can erode more shareholder value than anything else. In fact, the company is so meticulous about meeting GCP requirements that the clinical trial site is monitored by a clinical research associate, reviewed by a quality standards manager, audited by its auditors and then of course the regulator. Would a company risk damage to reputation by not adhering to the principles and spirit of GCP, when the same company has put in so much effort to formulate and update the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use? Even the protocol is not a company document but one that has inputs from prospective clinicians and regulators.

In the end, whose study is it anyway? Data Steering Committees and Data and Safety Management Boards can stop a trial for futility or safety reasons and negative studies do get published (evidence based medicine is no longer evidence biased medicine).

As a prominent person from the industry observed, Credibility begins with CR (clinical research). It also stands for Conflict Resolution among regulators, sponsors, CROs to see that the clinical research goes on; steering clear of the sensationalism, exploitation of individuals and organizations, controversies and aim at bringing the medicines within the reach of the common man!!!!!!!!!!!!

Biography

Mr. Krishna Prasad, CEO & Director, Cito Healthcare P Ltd is associated with the erstwhile SOL Pharmaceuticals Ltd, Nicholas Piramal India Ltd (Now Piramal Healthcare), Aurobindo Pharma Ltd, QPS Bioserve India Pvt Ltd, RACem Pharma Ltd (CRBio), ClinSync Clinical Research P Ltd in the fields of Commercial Management, Warehousing, Project Management, Human Resources, Administration, Business Development & Marketing.

kp@cithc.com