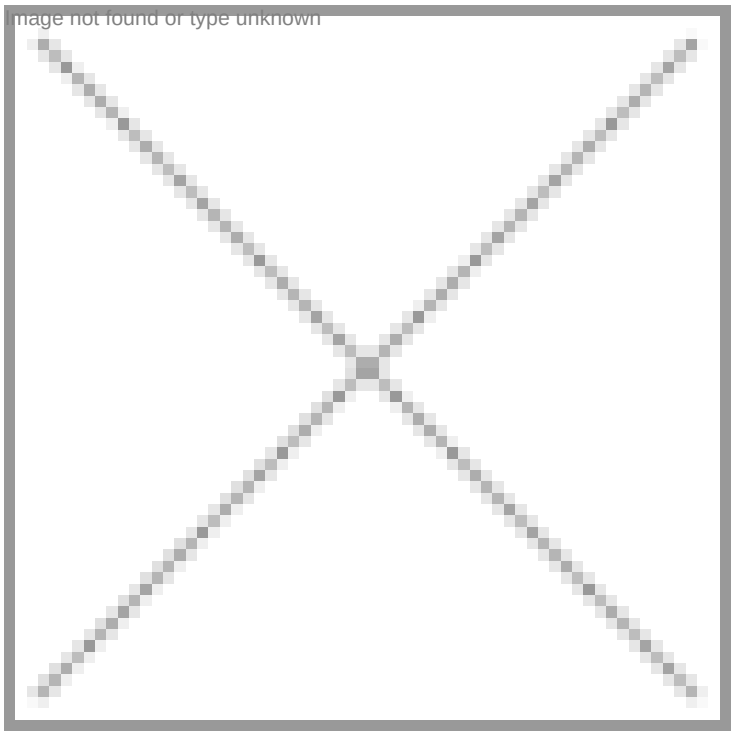
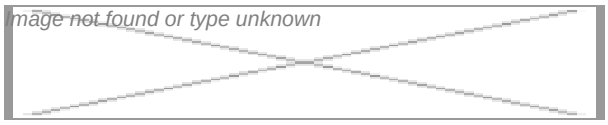
BioSpectrum
the business of Bio & Health Sciences

Clinical Trial Registry to bring transparency in India

08 September 2010 | News



Today, world over, there is a need for transparency, accountability and accessibility in order to re-establish public trust in clinical trial data.



Clinical trials hold enormous potential for benefiting patients, improving therapeutic regimens and ensuring advancement in medical practice, that is evidence-based.

However, the data and reports of various trials are often difficult to find. However, this tendency for availability of only selective information from the myriad clinical trials conducted, is not commensurate with the practice of “evidence-based medicine”. Today, world over, there is a need for transparency, accountability and accessibility in order to re-establish public trust in clinical trial data. And this would be feasible only if all clinical trials conducted, are registered in a centralized clinical trials registry.

Hence, Indian Council for Medical Research (ICMR)’s National Institute of Medical Statistics (NIMS) has set up a registry for clinical trials in June 2009. The registry will collect information on all prospective clinical trials to be conducted in India, and make this information available to the public. The Indian registry is planned to be a freely available and searchable primary register. To register a study, trialists need to submit information including the basic data required by the International Clinical Trial Registry Platform (ICTRP), and will receive a WHO-assigned unique identification number. In addition, Clinical Trials Registry, India (CTRI), will encourage trialists to include subsequent protocol amendments and give regular updates on the

status of trial.

Responding to the mandatory registry of clinical trials, Dr Sanjeev K Chaudhry, CEO, Super Religare Laboratories, notedthat the CTRI has many advantages as it gives an up-to-date information about the number of trials happening in India, along with the sites. It acts as a one-stop shop for those seeking information about clinical trials in the country. It enables transparency of data, and makes it available for publishing in reputed journals. If results are added after completion of the clinical trials, the total process would be open to scrutiny.

Having a similar view, Dr Apurva Shah, group managing director, Veeda Clinical Research, said: “Mandatory registration brings transparency in the system, gives confidence to the new entrants (sponsor); and gives the feel about the type of trials being conducted in India. At the operational level, it gives insight to the experience/capabilities of the investigator. At the business level, it gives information about the sponsors, CROs involved and the indications they are working on. On the whole it’s a very healthy thing, that will benefit all parties concerned.”

Dr Anand Bidarkar, vice president, Business Development, Siro Clinpharm, noted that it will bring about transparency, and also patients can look up the website for information on the ongoing trials and arrive at a decision, particularly patients who are in dire need to medicines.

Dr Vijai Kumar, chief medical officer and president, Excel Life Sciences, has different views. He says, “I don’t think it benefits the CRO industry as much as the general public. It helps the community at large, to know about the nature of trials going on in the country. It is directed towards increasing community awareness about clinical research and, can be used as a tool to encourage community participation.”

Sharing his thoughts on the process of registering for a trial, Dr Arun Bhatt, president, Clininvent, said, “The CTRI is not yet efficient in the process of registration. It takes a lot of time in completing the registration process. This has added extra work for the CROs. But the registration has brought about transparency in trial registration.”

On the other side of the mandatory registry of clinical trials, Ms Nidhi Saxena, founder and CEO, Karmic Life Sciences says, “Though it will bring transparency into the system, foreign companies have a fear of confidential data getting picked up by competitors. So there should be some element of discretion.”

In conclusion, setting up a Clinical Trials Registry would ensure that all clinical trials conducted in India are publicly declared and identifiable, and a minimum set of information of all clinical trials is freely available to physicians, health researchers, academicians, pharmaceutical industries as well as the common man. While bringing in transparency in the system, CTRI should try to address some of the concerns raised by the CROs.

Narayan Kulkarni
(with inputs from Nayantara Som, Rahul Koul & Jahanara Parveen)