

Correspondence

Clinical trial registration gains momentum in India

Sir,

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 and in some cases do not even exist as many trials are abandoned or are not published due to “negative” or equivocal results. As a result, only selective information is available from the numerous clinical trials conducted, which is not commensurate with the practice of “evidence-based medicine^{1,2}”. Further, with the unethical practices being adopted by the pharmaceutical companies for monetary gains coming to light, the public’s confidence in clinical trials results has suffered a tremendous setback. Rofecoxib’s ignominious withdrawal³, use of paroxetine in children despite evidence to the contrary being available with the company⁴ are a few examples of devious practices going on in the name of drug development.

As a direct consequence of these unfortunate events there has been a growing call for transparency, accountability and accessibility of clinical trials and their results in order to re-establish public trust in clinical trial data. This would be feasible only if all clinical trials conducted are registered in a centralized clinical trial registry before the enrollment of the first patient/volunteer. In keeping with the developments on the global front, a registry for clinical trials has been initiated by the ICMR’s National Institute of Medical Statistics (NIMS) and the Clinical Trials Registry – India (CTRI) was officially launched on the July 20th, 2007. The CTRI (www.ctri.in) is an online system for the registration of all clinical trials being conducted in India as well as neighbouring countries which do not have such registries of their own. Although the mandate is for the prospective registration of trials, *i.e.*, before the enrollment of the first patient in the trial, currently in the CTRI, ongoing and completed trials are also being registered.

Initially after the launch, only 11 trials were registered by the end of December 2007. All these trials were registered before the recruitment of the first patient. To increase trial registration, various dissemination workshops were organized in western, southern and eastern zone of the country resulting in direct impact on trial registration. The number of hits on the CTRI site crossed the 24000 mark till April 2009 with more than 600 users registered. Also, till April 2009 the registration of clinical trials rose to 235 as compared to 148 trials registered till December 2008. The number of trials registered were 11 (July-December 2007), 60 (January-June 2008), 77 (July-December 2008) and 87 (January-April 2009). About 100 trials are pending with the respective registrants for various modifications/clarifications, while 50 trials are pending with the Administrator awaiting Ethics Committee/Drug Control General of India (DCGI) approval.

Although registration of clinical trials in the CTRI is currently voluntary, registration of clinical trials is supported and recommended by various esteemed bodies. In February 2008, editors of 11 Indian biomedical journals came out in support of clinical trial registration. As an indication of their commitment towards transparency, accessibility and accountability of clinical trials, they have declared that “From January 2010 onwards, we will consider publication of a trial only if it has been registered prospectively if started in or after June 2008; trials undertaken before June 2008 need to be registered retrospectively”⁵.

Also, from November 2008 onwards, the Office of the DCGI, the highest drug regulatory authority in the country, has commenced advising interested parties seeking permission to conduct clinical trials to register their trial in the CTRI before initiation of the study. After this initiative by DCGI office, 87 trials were registered during four months (January to April 2009). There is

also a move by DCGI office to make trial registration mandatory after June 2009⁶⁻⁹. After the implementation of this move, a significant gain in momentum of trial registration under CTRI is expected.

The CTRI performs quality assurance on submitted entries, and has a mechanism for obtaining updated data and as well as performs deduplication of submitted trials. Deduplication is the process of identifying and removing duplicate sets of data belonging to the same trial. The Indian trial registration data set and the process of trial registration has been discussed in detail elsewhere¹⁰. In addition, guidelines are being notified by the DCGI to make contract research organizations (CROs) registration mandatory resulting in quality clinical trials. Another important milestone for the CTRI is that since December 2008, trials registered in the CTRI are also searchable from the WHO's global search portal, the ICTRP¹¹. In conclusion, setting up of the CTRI is a meaningful step towards greater transparency and accountability in clinical trials and their scientific process¹².

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