Challenges in Administering a Clinical Trials Registry: Lessons from the Clinical Trials Registry-India

Abstract

The Clinical Trials Registry - India (CTRI), an online system (www.ctri.nic.in) for the registration of clinical trials being conducted in India, has its secretariat at the National Institute of Medical Statistics of the Indian Council of Medical Research in New Delhi. The primary objective of the CTRI is to ensure that all clinical trials conducted in India are registered in order to bring transparency, accountability and access to clinical trials. Since its launch on 20 July 2007, the CTRI has gone from strength to strength and, as of January 2013, more than 3,300 trials had been registered. Although initiated as a voluntary exercise, registration of trials requiring approval by the drug regulatory authority in India has been made mandatory. Editors from 11 major biomedical journals in India require submission of the clinical trial registration number as a prerequisite for publication. In addition, several ethics committees also insist upon trial registration. The CTRI is a primary registry of the WHO's International Clinical Trials Registry Platform. This article discusses the challenges encountered during the setting up of the CTRI and the strategies adopted, and also explains the steps to trial registration in the CTRI.

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