

PLANNING A CLINICAL TRIAL! PLEASE REGISTER BEFORE ENROLLING

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Go ahead and click-on www.ctri.in – the website of the Clinical Trial Registry of India. The registration is easy, free, on-line and voluntary.

Why should you register?

By registering your trial, you are contributing to generation of evidences for decision-making. If all of us register, then these open access clinical trial registries are likely to have information to address ethical and scientific problems which arise when trial results are either delayed or not completely revealed to public or researchers; when volunteers consent to a trial with the understanding that the study will inform medical knowledge and then the results are not made public; future volunteers are at risk for being misled and harmed when their consent and trial design are not fully informed by prior research; ethical committee members are unable to weigh the risks and benefits when some unknown proportion of relevant data is unavailable for review¹.

Clinical trials Registers

On 20th July 2007, India joined a select group of countries like Australia, United Kingdom and United States of America that have made provisions for registering clinical trials.

For various well known reasons, India is emerging as one of the most preferred sites for conducting clinical trials. Globally, pharmaceutical companies are under immense competitive pressure to develop interventions and market them quickly. In this haste scientific, ethical and regulatory principles, at times, have and are being compromised especially by the 'fly by night' investigators. Communities in developing countries fall easy prey to them. Some of these trials have caught national and international attention and have succeeded in whipping up considerable public

debate. One of the recommended options to curb the menace of such incidents is to encourage registration of all interventional trials.

There are several hundred registers of clinical trials around the world, but each has been started with different objectives and philosophy. They collect varied information to meet their objectives.

International Committee of Medical Journal Editors

The crusade of increased transparency and accountability in conduct of clinical trials received a shot in the arm when the International Committee of Medical Journal Editors (ICMJE) proposed a comprehensive trials registration as a solution to problem of selective awareness and announced that all eleven ICMJE member journals will adopt a trials registration policy to promote this goal².

This Policy applies to any clinical trial starting enrolment after July 1, 2005. The ICMJE did not advocate any particular registry but did lay down the minimum parameters which it must meet. Though ICMJE established policy for its member journals, many other journals have adopted the trial registration recommendation.

Two years after the ICMJE laid down its guiding principles it re-evaluated its policy in mid-2007. It concludes that the research community has embraced trial registration. This is evident from the sharp increase in the numbers of clinical trials which have been registered in five major registries that met the ICMJE's criteria³.

International Clinical Trial Registry Platform

Around the same time as the ICMJE's policy statement the WHO's initiative of International Clinical Trial Registry Platform had been launched,

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aimed at standardizing the way information on medical studies is made available to the public through a process of registration. Within two years' time this too has developed. It has recommended 20 key details to be disclosed at the time studies begin. The WHO's effort aims to bring uniformity in the data being recorded in each registry by providing a set of standards for all registers. In addition, it is developing into a network of primary and partner registers that meet the WHO-specified criteria⁴.

Primary registers are the WHO-selected registers managed by not-for-profit entities that will accept registration for any international trials, delete duplicate entries from their own register and provide data directly to the WHO. The ICMJE will accept registration of clinical trials in any of these primary registers. Partner registers, on the other hand, are registers that submit data to primary registers but limit their own register to trials in a restricted area (such as a specific disease, company, academic institutions or geographic region). Registration in a partner register is insufficient³.

Clinical Trials Registry – India

The Clinical Trials Registry – India (CTRI) meets the requirements of WHO of a Primary Register (along with Australian, New Zealand Clinical Trials Registry, Chinese Clinical Trial Register, and ISRCTN.org; although not a primary register, data from United States National Library of Medicine sponsored ClinicalTrials.gov is also included in the WHO Search Portal)⁵.

Hosted by the National Institute of Medical Statistics – one of the 26 permanent institutes of the Indian Council of Medical Research (ICMR), the CTRI requires declaration of few additional items (than the WHO mandated 20 issues) before enrollment of the first patient. Thus to register a study, trailists will need to submit information as per the requirements of Registrational Data set. Some fields are mandatory for registration. If all the necessary fields are filled with valid and informative entries, the trial will be officially registered and allocated a unique registration number.

Incomplete entries receive a provisional registration number. The provisional registration number does not suffice for purposes of publication in journals that endorse the ICMJE recommendations for trial registration. The CTRI is scalable to cover other countries in the region.

The setting up of this Registry is an eloquent example of inter-agency collaboration and is jointly funded by the Department of Science & Technology, Ministry of Science and Technology; the World Health Organization and the Indian Council of Medical Research.

All interventional clinical trials conducted in India and involving Indian participants should be registered. The Clinical Trial Registry - India would go along with the ICMJE's decision to implement the WHO definition of clinical trials that begin enrolment on or after July 1, 2008, This definition states that "an interventional clinical trial is any research study that prospectively assigns people to one or more wealth health related interventions to evaluate their effects on health related outcomes"³. Examples include, but are not limited to preventable care, drugs (including herbal), surgical procedures, behaviour treatments, medical devices, etc). All phases of trials, trials of marketed or non-marketed products, randomized or non-randomized trials – all should be registered. If in doubt, register.

Putting in place a clinical trial registry is unlikely to solve all problems. A number of trials may never get registered (as registration is voluntary). The issue of incomplete disclosure of results would persist. Unanticipated adverse events may not be recognized due to relatively small sample sizes and incomplete publications of results from pre-approval studies. Important lessons are being learnt from the registries which have been in operation for a long time^{1,3}.

Universalization of clinical trials needs actions at various levels. Some 'push' and 'pull' mechanisms like legislative steps and incentives may be helpful. Ethical committees can encourage investigators to register and so can the funding and regulatory agencies. The editors of biomedical

journals can adopt the ICMJE policy and insist on a registration number. Each one of us can and should do our bit and contribute towards bringing in greater transparency and public trust in conduct of clinical trials.

REFERENCES

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TUBERCULOSIS HEALTH VISITORS' COURSE

The 2008-2009 Tuberculosis Health Visitors' Course of nine months' duration will be conducted at the New Delhi Tuberculosis Centre. The minimum qualification for admission to this course is 10 + 2 with science and/or hygiene. Science education up to class 10 is essential. Application forms for admission to the course can be obtained from the Secretary General, Tuberculosis Association of India, 3, Red Cross Road, New Delhi-110 001. The last date for receipt of applications is 30th April, 2008.