

CLINICAL TRIAL REGISTRATION

When to and why register

Clinical trials have been described lately as the gold standard in the evaluation of issues related to treatment and prevention in health¹. The registration of clinical trials has been suggested with the intention of respecting ethical reasons for those who participated in the study and were informed that they would be used to contribute to the advance of science, regardless of the results. It is also a way of guaranteeing that patients and professionals have access to information on studies which are recruiting volunteers for research, as well as trying to avoid the duplication of efforts of performing studies already conducted in the past, stimulating scientific knowledge and cooperation among research groups².

The registration of clinical trials allows the identification of gaps in the existing knowledge in different areas, the observation of trends in the field of studies and the identification of specialists in the various areas³.

According to the World Health Organization (WHO), randomized control trials and clinical trials must be announced and registered before being commenced. This will allow the identification of all clinical trials underway and their respective results, since not all of them are published in scientific journals. The *International Committee of Medical Journal Editors* (ICMJE) suggests that scientific journal editors require from authors the registration number at the time of submission of papers⁴.

Recently the editors of peer-reviewed journals in the Lilacs and Scielo databases, such as the Brazilian Journal of Physical Therapy, received an official report stating that BIREME (Regional Library of Medicine) would begin requiring from journals that publish randomized control trials and clinical trials that they include, in the instruction to the authors, the recommendation for prior registration of clinical trials and that they request the identification number as condition of acceptance of the manuscript. This decision follows the instruction of WHO's and ICMJE's International Clinical Trials Registry Platform (ICTRP). ICMJE defines as a clinical trial every research project that is prospective and assigns patients to clinical or drug intervention, which may interfere in their health, with the purpose of comparing the cause/effect among studied groups.

ICMJE stated, in 2004, that its member journals would only accept for publication trials registered in freely accessible public registries, managed by non-profit organizations, having at their disposal mechanisms for validation of registered data and that allow electronic searches⁵.

WHO proposes a minimal set of information that must be registered on each trial, such as: unique identification number, trial registration date, secondary identities, sources of financing and support material, main sponsor, other sponsors, contact details for public queries, contact details for scientific queries, the study's public title, the scientific title, recruitment countries, health problems studied, interventions, inclusion and exclusion criteria, type of study, date of recruitment of first volunteer, intended sample size, recruitment status and primary and secondary result measurements.

With the purpose of providing greater visibility to validated Clinical Trial Registries, WHO launched its *Clinical Trial Search Portal* (<http://www.who.int/ictrp/network/en/index.html>), with an interface which allows simultaneous searches in various registries. In this portal, searches can be made by words, clinical trial title or identification number. The result shows all existing trials, in different phases of execution, with links to the full description in the corresponding Primary Clinical Trial Registry. WHO created its *Network of Collaborating Clinical Trial Registers*, which

will allow the exchange between Clinical Trial Registry producers in order to define good practices and quality control. The websites for primary clinical trial registration are: www.actr.org.au (*Australian Clinical Trials Registry*) (Figures 1 and 2), www.clinicaltrials.gov (Figures 3 and 4) and <http://isrctn.org> (*International Standard Randomised Controlled Trial Number Register* (ISRCTN)) (Figures 5 and 6). National registries are being created and, where possible, their registered clinical trials will be forwarded to those recommended by WHO.

The proposal by WHO, backed by PAHO (Pan-American Health Organization), has received support in the Americas. LATINREC – The Latin American Ongoing Clinical Trial Register – was created and developed by the Colombian branch of the Iberoamerican Cochrane Collaboration. This registry is about to start its operations, following ICTRP requirements. Canada has also adhered to the proposal, but is considering how to implement it⁶.

In Brazil, discussions on the WHO proposal are being held not only by the authorities responsible for the Department of Sciences and Technology (DECIT), the Science, Technology and Strategic Input Bureau (CTIE), the Health Ministry, the National Health Surveillance Agency (ANVISA) and the National Council of Ethics in Research (CONEP), but also by editors, representatives of the industry, of the patients, of foreign (Latinrec and SANCTR) and national (ICICT/FIOCRUZ) registries, and of researchers; in short, a significant number of interested parties, resulting in the decision to create a national registry. However, several measures need to be established for the implementation of a National Registry, including the Country's registration policy⁶. Steps are being taken to bring this to fruition and to increase the visibility of the clinical trials undertaken within the national territory and by Brazilian researchers.

There are countless registered clinical trials already in existence, including those in the area of physical therapy and rehabilitation as a whole. There are few registrations by Brazilian physical therapists, but this outlook is certainly undergoing rapid changes especially given the fact that, at the last International Public Health Conference, the Latin American journals agreed to accept only registered clinical trials for publication within a year.

Maria Stella Peccin

*Health Sciences Department
Federal University of São Paulo*

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