A Milestone for Clinical Trials: Establishment of A Global Clinical Trial Registration System

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In May 2007, the World Health Organization International Clinical Trial Registry Platform (WHO ICTRP) was formally launched. The Australian and New Zealand Clinical Trials Registry (ACTR), ClinicalTrials.gov of National Library of Medicine, United States, and International Standard Randomised Controlled Trial Number Register (ICRCTN), United Kingdom, were certified as the first three Primary Registers. In June 2007, as the Ministry of Health of China sponsored national clinical trial register, the Chinese Clinical Trial Register (ChiCTR) was accepted as the fourth WHO ICTRP Primary Register.

The launching of WHO ICTRP symbolizes the founding of a global clinical trial registration system which registers clinical trials according to the consolidated standards and grants a unique registration number.

1. A milestone event for clinical trials

Since the establishment of the Physician Data Query Cancer Clinical Trials Registry by the National Cancer Institute (NCI) for the register of cancer clinical trials in 1977, hundreds of registries including ClinicalTrils.gov, ISRCTN, ACTR and ChiCTR have been set up during the past ten years.

From July 1st, 2005, the member journals of the International Committee of Medical Journal Editors (ICMJE) began to adopt a policy that all trials should be registered in a public trials registry at or before the onset of patient enrollment before considering the trial for publication. The Statement, declared by ICMJE, was to thank the altruistic participants who have placed themselves at risk by volunteering for clinical trials, and also to reveal the existence of all clinical studies, even those that reflect unfavorably on a research sponsor's product, so as to avoid the distortion of the body of evidence available for clinical decision making.

In the Ministerial Summit on Health Research that took place in Mexico City in November 2004, participants called for the WHO to facilitate the establishment of "a network of international clinical trials registers to ensure a single point of access and the unambiguous identification of trials". Following the Summit, the Secretariat of WHO ICTRP was established in August 1st, 2005, and stated the purposes of clinical trial registration:

“The primary objective of the WHO Registry Platform is to facilitate the prospective registration of a minimum amount of information on all clinical trials, and the public accessibility of that information. It also advocates for the public availability of a minimum amount of results information from clinical trials. “

“The WHO Registry Platform will work with stakeholders to agree on an internationally appropriate norms and standards for trial registration and results reporting that uphold scientific and ethical principles. “

Clinical trial is the basis for advancements in medical science. It is related to both the respect for individual contributors who altruistically volunteered for clinical trials, and also to the human being’s health enterprise because the results of each individual clinical trial may be used to treat others. Thus, each clinical trial itself is a public event with social attribution, and everybody has the right to know the detailed information about each trial’s implementation process and results. Publicizing the sponsor, study site(s) and other information on the trial is a responsibility to human beings. It is a big advance in the acknowledgement of medical science that a clinical trial should be no longer treated as an individual behaviour and each trial should be managed in an orderly way. The global clinical trial registration system will exert a profound influence on the medical science as a whole. It reflects the social responsibility, humanism and international cooperation spirit of all governments, medical scientists and medical journal editors all over the world. It’s a huge contribution to the health enterprise of all human beings, and also a milestone event in the clinical trial field in the 21st century.

2. WHO ICTRP

The WHO ICTRP takes the lead in setting international norms and standards for trial registration and reporting, a register certification process, a unique ID numbering scheme and assignment process, and data interchange standards.

The WHO ICTRP has 2 key elements: the WHO Network of Collaborating Clinical Trial Registers (the Register Network) and the Search Portal. The search portal itself is not a registry but a conduit for users to search the central database (the WHO ICTRP Central Repository), which contains the trial registration data sets provided by the Contributing Registers. When a search is conducted and a trial identified, users can click on a hyperlink that will direct them to the relevant record in the source register from which the trial came.

The WHO ICTRP mainly consists of Primary Registers and Partner Registers, both of which are called as Contributing Registers. The Primary Register is responsible for trial registration and submits data to the Central Repository, while the Partner Register has to submit data via Primary Register to the Central Repository.

Figure 1 presents the framework of the WHO ICTRP:

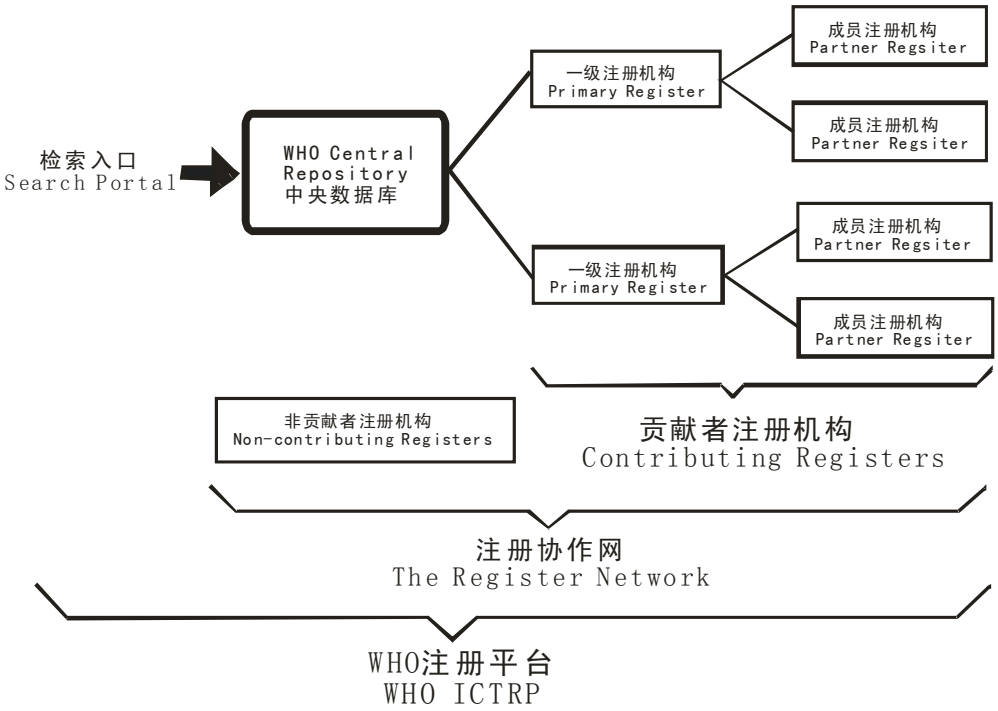

Figure 1. Framework of the WHO ICTRP

3. Chinese Clinical Trial Register (ChiCTR)

ChiCTR was launched in October 2005. The mission of ChiCTR is to “Unite clinicians, clinical epidemiologists, biostatisticians, epidemiologists and health care managers, to manage clinical trials and promote their quality in China, so as to provide reliable evidences from clinical trials for health care workers, consumers and medical policy decision makers, and also to use medical resources more effectively to provide better service for Chinese people and all human beings.”

As a WHO ICTRP Primary Register and the national clinical trial register, ChiCTR is responsible for promoting the quality of the design and conduct of clinical trials in China, also for the management of the information relevant to these trials. West China Hospital of Sichuan University, where the ChiCTR located, is the source and main training base of clinical research methodology and evidence-based medicine in China. Based on the technical platform, consisting of Chinese Evidence-based Medicine Centre of Ministry of Health of China, Chinese Cochrane Centre and International Clinical Epidemiology Network Resource and Training Center in West China Hospital (INCLEN CERTC), ChiCTR united 48 (now extended to 52) key medical journals and jointly launched the Chinese Clinical Trial Registration and Publication Collaboration (CHICTRPC) in April 2006, so as to establish a registration and publication system for clinical trials in China. The system is initiated to promote the Good Publication Practice (GPP) and control the quality of clinical trials both at the entrance and the exit: ChiCTR is responsible for registration of clinical trials, consultation on the trial design, provision of central randomization service, and guidance on the writing of clinical trial reports. As the exit of clinical trials, medical journals are obliged to monitor the registration of trials, and together with ChiCTR to guide the writing and publication of trial reports.

Now, the ChiCTR and CHICTRPC are welcoming more medical journals to join the Collaboration so as to fully implement the clinical trial registration system in China as early as possible.