Special Article

Trials Registration: A New Era in Thailand

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Registration of clinical trials or research can result in many benefits. Patients have access to pertinent information. We have a better and more indicative picture of research status in areas where registration is mandatory. Researchers can use the information to form a common interest group and collaborate their research as well as to avoid unnecessary duplication. Registered information can also enable detection of defective design and can lead to improvements of trial protocol or its implementation. Most importantly, it can help to reduce problems of publication bias and selective reporting. Journals do not like to publish negative or inconclusive results. Pharmaceutical companies are reluctant to report results that may jeopardize their revenue. We need absolute transparency to utilize evidence with trust.

Keywords: *Trials registration, Primary registry, TCTR*

J Med Assoc Thai 2013; 96 (10): 1385-7
Full text. e-Journal: *http://jmat.mat.or.th*

In 2004, the International Committee of Medical Journal Editors (ICMJE), a group of then 11 influential journals, issued a statement that all clinical trials must be registered before enrolling the first patient[1]. With no registration, the manuscript would not be considered for publication in the member journals. The policy was later added to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM) and has since been adopted by hundreds of journals[2,3]. In October 2008, the revised Declaration of Helsinki stated that "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject[4]". The Journal of the Medical Association of Thailand has supported the idea of clinical trial registration since 2010 and from August 2010, authors submitting manuscripts with clinical trial settings have had to supply the journal with trial registration information[5].

Not all the researches have to be registered. A purely observational study is not required to be registered. The ICMJE group had their own definition of clinical trials to start with but since 2007, they have adopted the definition provided by World Health Organization (WHO). It says, "For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, and preventive care, etc. This definition includes Phase I to Phase IV trials[6]".

ICMJE also specifies which registries are acceptable. In addition to the primary registries in the WHO's International Clinical Trials Registry Platform (ICTRP), there are also a few other accepted registries. Many countries, e.g. Australia, Brazil, China, Germany, Japan, and Korea, etc., have their own national registries listed as a primary registry on WHO portal site. Any countries who want to enforce registrations by means of regulations and laws will need to have their own and self-maintained registry.

In August 2007, Thai Food and Drug Administration convened a meeting to explore the possibility of establishing a national trials registry. The meeting was attended by all stakeholders, e.g. research funding agencies, pharmaceutical industry, Ministry of Public Health, and university researchers. However, there was no consensus and no further meeting was held. In 2009, a group of university academics in Thailand was formed to set up a Thai national registry, the Thai Clinical Trials Registry (TCTR, http://www.clinicaltrials.in.th). TCTR is

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funded by the Thailand Center of Excellence for Life Sciences (TCELS, http://www.tcels.or.th), and run by the Medical Research Foundation (MRF, http://www.mrf.in.th). In December 2010, the Ministry of Public Health endorsed the project. TCTR aims to promote all the aforementioned benefits of a research registration so that we accept and support all kinds of research and research designs, not limited to only clinical trials[7]. Researchers can register their studies at any time but for clinical trials, to comply with ICMJE's URM, they must be registered before the first subject is enrolled into the study. We also have a hotline telephone number with personal assistance, if researchers have any difficulties during the registration process. Registration with TCTR has been and will be, for a foreseeable future, free of charge. As of July 2013, TCTR has 65 studies registered with it as a primary site.

On August 7, 2013, WHO officially announced TCTR one of its primary registries, having passed all of the WHO ICTRP requirements, e.g. data integrity, safety, robustness, etc. Clinical trials researchers now no longer have to go to foreign web sites to register their trials; having our own national registry will surely bring forth a new era for researchers in Thailand, in which research transparency and accountability can be independently maintained.

Potential conflicts of interest

None.

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ทะเบียนงานวิจัยคลินิก: ศักราชใหม่แห่งวงการวิจัยไทย

กิตติศักดิ์ กุลวิชิต, วสี ตุลวรรธนะ, บัณฑิต ถิ่นคำรพ, ปิยทัศน์ ทัศนาวิวัฒน์

การลงทะเบียนงานวิจัยก่อให้เกิดประโยชน์หลายประการด้วยกัน แต่ประโยชน์สูงสุดที่เป็นเหตุให้กลุ่ม International Committee of Medical Journal Editors (ICMJE) ประกาศไม่รับพิจารณาตีพิมพ์งานวิจัยทางคลินิกที่ไม่ลงทะเบียนก่อนเริ่มวิจัยตั้งแต่ปี พ.ศ. 2547 เป็นต้นมา ก็คือการที่บริษัทยาเลือกตีพิมพ์เฉพาะผลการศึกษาที่ได้ประโยชน์ และเก็บซ่อนงานศึกษาที่ได้ผลในทางลบต่อบริษัท ทั้งนี้ ICMJE ยังระบุว่า registry ที่เป็น primary registry ของ WHO's International Clinical Trials Registry Platform (ICTRP) จะได้รับการยอมรับจาก ICMJE หลังจากนั้นก็มีวารสารทางการแพทย์ประกาศหลักการเดียวกันอีกหลายพันวารสาร รวมทั้ง จพสท. ด้วย กลุ่มนักวิชาการและนักวิจัยไทยได้รวมตัวกันก่อตั้ง Thai Clinical Trials Registry (TCTR, http://www.clinicaltrials.in.th) ซึ่งได้รับการสนับสนุนจาก Thailand Center of Excellence for Life Sciences (TCELS) ร่วมกับมูลนิธิส่งเสริมวิจัยทางการแพทย์ และได้ทำการยื่นขอเป็น primary registry ของ WHO ICTRP โดยได้ผ่านการตรวจสอบรับรองจาก WHO เป็นที่เรียบร้อยแล้ว WHO ได้ประกาศรับรอง TCTR เป็น primary registry อย่างเป็นทางการเมื่อวันที่ 7 สิงหาคม พ.ศ. 2556 ซึ่งหมายความว่านับแต่นี้ต่อไปนักวิจัยไทยไม่มีความจำเป็นที่จะต้องไปลงทะเบียนในฐานข้อมูลต่างชาติเพื่อให้เป็นตามข้อบังคับ ICMJE อีกต่อไป