

ORIGINAL ARTICLE

Establishing the Sri Lanka Clinical Trials RegistryUdaya K Ranawaka¹ and Colvin Goonaratna²¹ Administrator and Secretary of Sri Lanka Clinical Trials Registry and Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka;² Chairperson of Sri Lanka Clinical Trials Registry and Faculty of Medicine, University of Colombo, Colombo, Sri Lanka**Keywords**

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Abstract

Recognizing the need for a national body for trial registration, the Sri Lanka Medical Association took up the challenge of setting up the Sri Lanka Clinical Trials Registry. The registry was established in November 2006, the first functioning trial registry in South Asia. The Sri Lanka Clinical Trials Registry is now a primary registry affiliated to the Registry Network of the International Clinical Trials Registry Platform of the World Health Organization. The Sri Lanka Clinical Trials Registry has not been a mere repository for trial data but has also had a positive influence on the research community in Sri Lanka.

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Mandatory trial registration: a call for greater transparency in clinical trials

Mandatory registration of clinical trials has come to stay. After a rather long conception and difficult labor, it has finally seen the light of day. And it has been welcomed into the world of clinical trials by researchers, academia, clinicians, and even the pharmaceuticals industry, albeit after much initial skepticism. Like any success story, it has many parents. Many isolated requests for greater transparency in clinical trials date back to the early 1970s (1, 2). The call gathered momentum with each new therapeutic mishap related to selective reporting, and there became enough of them to convince even the most ardent opponents (3–5). A major impetus, of course, came with the decision of the International Committee of Medical Journal Editors (ICMJE) that all clinical trials involving humans should be prospectively registered before they can be considered for publication (6, 7). The World Health Organization (WHO) strongly supported the ICMJE stance, declaring “registration of all interventional trials a scientific, ethical, and moral responsibility” (8,

9). The WHO has successfully marshaled activities under the banner of the International Clinical Trials Registry Platform (WHO-ICTRP) (9). It has also laid the ground rules for registration by specifying the minimum criteria for a registry: the WHO-ICTRP minimum data set.

The benefits of prospective trial registration are many (6, 9–11), and the concept has now been embraced by the scientific community. It is heartening to note that the WHO has been able to bring together different countries, and national registries have been established in countries with different socioeconomic backgrounds (12). The call for mandatory trial registration has received a major boost by the recently amended Declaration of Helsinki, stating “every clinical trial must be registered in a publicly accessible database before recruitment of the first subject” (13).

Sri Lanka Clinical Trials Registry: the beginning

The Ceylon Medical Journal (CMJ) first raised the call for a national body for trial registration in Sri Lanka in 2005 (14). The CMJ is committed to abiding by the ICMJE guidelines in

medical publishing, and in the wake of the ICMJE declaration on trial registration (6), called upon the Sri Lanka Medical Association (SLMA) to take up this challenge in its capacity as the premiere professional medical organization in the country. After deliberation, the SLMA decided to establish the Sri Lanka Clinical Trials Registry (SLCTR). A committee of academics and scientists was appointed in August 2006 to establish and manage the SLCTR (the SLCTR Committee), with representation from the Ministry of Health, Postgraduate Institute of Medicine, universities, ethics review committees, and other professional bodies. Designing an internet-based registry with online facilities for the submission of trial applications, review, and registration was always going to be an onerous task and was outsourced to the web design team of Sri Lanka Telecom, the main telecommunications provider in the country. The SLCTR has been operational from November 2006, and was the first functioning clinical trials registry in South Asia. It is a matter of pride to us that the SLMA was able to establish a clinical trials registry in a developing country like Sri Lanka, without any external support. The SLCTR was recognized as a primary registry by the WHO-ICTRP in March 2008.

SLCTR now

The SLCTR is an internet-based, not-for-profit registry providing free access to researchers, clinicians, funding agencies, and the public at www.slctr.lk/. It welcomes registration of trials conducted in Sri Lanka and overseas. It has been designed to meet the requirements specified by the WHO-ICTRP and the ICMJE. In addition to the minimum WHO data set, it records details of ethics review committee approval and solicits regular progress reports from investigators. The SLCTR accepts only clinical trials with a health-related intervention and does not register observational studies. After an initial grace period where researchers were allowed to register trials after starting recruitment, it now accepts only prospective trial registration. All trial applications are evaluated by the SLCTR Committee, which meets regularly. The website is currently undergoing further development, and new features will include links to progress reports of ongoing trials and publications for completed trials.

Role of SLCTR in Sri Lanka

Sri Lanka is a developing country with limited resources. It has a per capita GDP of USD 196, a per capita annual health expenditure of USD 51, and 0.6 doctors per thousand people (15, 16). In spite of the relative lack of resources, it continues to be an example in terms of healthcare and social development; its health indicators, literacy rates, and

gender equality ratios are among the best in the developing world, especially South Asia (15, 16). The foundations of the medical establishment are old and strong. For example, the SLMA is the oldest professional medical association in Australasia, and the CMJ is the oldest medical journal in Australasia. There is a vibrant medical research culture, and clinical trials with international collaboration are flourishing.

The SLCTR has provided local researchers with a readily accessible national registry, and many trials have been registered to date. The registry has played the key role in creating awareness of the need for trial registration, with several presentations at scientific meetings, journal publications (11, 14), and regular updates in newsletters. However, the establishment of the SLCTR appears to have had a much more profound impact on the research culture within the country. It has re-invigorated discussion on clinical trials, ethics in research, and research publication at scientific meetings. Most ethics review committees in the country have started granting only conditional approval for clinical trial applications, with full approval subject to registration with a publicly accessible registry.

SLCTR: challenges ahead

Funding, and therefore, staffing, are problems that the SLCTR will continue to grapple with, as the SLMA is a not-for-profit institution. Fortunately, the Ministry of Health and the WHO have come forward to help ease the burden. With the affiliation to the WHO-ICTRP as a primary registry, the SLCTR has to develop mechanisms for uploading data to the ICTRP. This has created a new set of challenges for the web design team. Initial difficulties were easily forgotten amidst the success of establishing the Registry and its recognition as a primary registry by the WHO. Keeping the momentum will be more difficult. Improving awareness among the scientific community about trial registration needs more emphasis. The SLCTR is determined to go forward despite these challenges, and the co-operation of clinicians, researchers, health care planners, patients, and the public will be vital.

Conflict of interests: None.

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