JOURNAL OF EVIDENCE-BASED MEDICINE

Journal of Evidence-Based Medicine ISSN 1756-5391

# The Sri Lanka Clinical Trials Registry – Moving forward

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Received 25 May 2011; revised 30 June 2011; accepted for publication 29 July 2011.

doi: 10.1111/j.1756-5391.2011.01141.x

## Abstract

The Sri Lanka Clinical Trials Registry (SLCTR) is a Primary Registry in the Registry Network of the World Health Organization's International Clinical Trials Registry Platform (WHO-ICTRP), and regularly feeds data to its Clinical Trials Search Portal. Over the last few years, the SLCTR has been able to achieve its original objective of providing a national trial register for Sri Lankan researchers, but its role has always been more than that of a mere storehouse of trial data. The research landscape is rapidly changing in Sri Lanka, and the SLCTR has been a key stimulus to a resurgent interest in clinical research among the Sri Lankan research community. The SLCTR is working together with its partner stakeholders to facilitate research in the country, and to ensure that clinical trials conducted in Sri Lanka meet the highest ethical and scientific standards.

## The journey so far

The Sri Lanka Clinical Trials Registry (SLCTR) was formed as an initiative of the Sri Lanka Medical Association (SLMA), with whole-hearted support from the Ministry of Health of Sri Lanka. Its establishment has been previously discussed in detail (1,2). It has been operational from November 2006, and was the first functioning clinical trials registry in South Asia.

The SLCTR was recognized as a Primary Registry in the Registry Network of the World Health Organization's International Clinical Trials Registry Platform (WHO-ICTRP) in March 2008, and regularly feeds data to its Clinical Trials Search Portal. It is an internet-based, not-for-profit registry, with free access to researchers, clinicians, funding agencies, patients and the public (http://www.slctr.lk). The SLCTR is managed by the SLMA, which is the apex medical professional association in Sri Lanka. Its activities are overseen by an advisory committee consisting of senior healthcare professionals nominated by the SLMA (the SLCTR Committee), which meets regularly to discuss trial data and operational activities, and to advise on policy. As of June 2011, the SLCTR has registered 64 trials, with twelve of them being registered in 2010 and nine in the first half of 2011. Several of them are international multicentre collaborative trials.

The SLCTR works in close cooperation with the WHO-ICTRP. The Registry website was designed to meet the requirements of the ICTRP, and has undergone several changes as the ICTRP requirements have evolved over the past few years. The SLCTR trial record contains all the data elements of the WHO trial registration data set (WHO-TRDS). In addition, each trial record contains details of ethics committee approval, trial progress, protocol changes and resulting publications. Several quality improvement initiatives were undertaken recently to meet the standards recommended by the WHO-ICTRP. They include updating of the standard operational procedures, and an internal audit of data quality and operational processes.

## The changing landscape of clinical trials in Sri Lanka

The SLCTR can legitimately claim to be a key stimulus to an ongoing dialogue on clinical research among Sri Lankan researchers, clinicians, professional associations, administrators and health care planners. Sri Lanka is currently witnessing an influx of international collaborative research. Its comprehensive primary health care coverage, educated populace, comparatively low cost of conducting research, and a core of competent and committed clinical researchers are the main advantages Sri Lanka offers, although one must

be mindful that such an influx can also be due to a perception of a different set of attractants often associated with developing countries, such as lax regulatory mechanisms, lack of ethical oversight and a vulnerable participant base (3). Creating an environment conducive to research collaboration while ensuring the safe and ethical conduct of clinical trials has been a recurring theme for discussion and debate in the country.

The Ministry of Health has recently taken several steps to strengthen the regulatory mechanisms governing clinical research. A Subcommittee on Clinical Trials (SCOCT) was established at the Ministry, which currently approves, oversees and regulates clinical trials. A new legal framework for the conduct of clinical trials is being drafted, and importantly, this is being done with inputs from different stakeholder groups including administrators, health planners, clinicians, researchers and professional organizations. The need to improve ethical oversight of clinical research has been recognized, and the SCOCT has taken several measures to support and strengthen the existing ethics review committees. The SLCTR has been an active and committed participant in all these activities.

A rapid increase in the volume of clinical research also brings in a different set of challenges – of developing research infrastructure and strengthening research capability of health care professionals, as well as improving clinical care facilities with infusion of newer technologies and treatment modalities. The SLCTR views these as opportunities for capacity building that will ultimately lead to better patient care in the country.

## Challenges so far, and challenges ahead

Sri Lanka is a developing middle-income country, and funding and technical capacity are obvious concerns for the SLCTR which have already been described. (1,2) But they are not the only constraints faced by a fledgling trial registry in a developing country (4,5). Political commitment for the process of registration is essential (5). The SLCTR has been fortunate in this respect, with the Ministry of Health fully supporting it from its inception. Credibility in the eyes of researchers, clinicians, other stakeholders and the public is important, and the close links forged with the SLMA and the Ministry of Health has enabled the SLCTR to establish its own identity among the research community.

Many of the challenges, however, are common to all trial registries, irrespective of their location, national remit or resources. Ensuring data quality is the main task of a registry, but the available evidence suggests that this is not easily achieved. Poor data quality would diminish the efforts of registries in achieving transparency in clinical trials (6–8). Previous studies have emphasized deficiencies in the quality of trial data recorded in primary registries (7–10). An internal audit of the SLCTR has identified several areas that need improvement, including quality of trial records and operational processes. Remedial measures have already been implemented or are under way to overcome these shortcomings.

The WHO-TRDS is only a first step towards better transparency (4,6,9,11), and there is a growing demand for availability of more trial data in the public domain (6,9,12,13). The SLCTR currently displays information on protocol changes and trial progress, details of regulatory bodies responsible for trial oversight, and trial results in the form of research abstracts or publications. Publication of full trial protocols as suggested by the Ottawa group (12) will be a further step in this direction, but the reactions to this proposition have been mixed (13,14). It is a challenge for the WHO-ICTRP and the partner registries in the Registry Network to develop a mechanism for displaying more comprehensive trial data which is acceptable to all segments of the research community.

Several countries require that all clinical trials conducted within the country are registered in their national registry (3,9,11). There are several arguments to support such a process (3,7,11). Ministries of Health have a national responsibility to ensure the conduct of ethical and scientific research, and a registry is ideally placed to support this by improving research transparency at a national level. A single point of access for all clinical trials conducted in the country would greatly help researchers, ethics review committees and funding organizations alike in identifying local research needs and in prioritizing allocation of available resources. It would also improve coverage of trial registration, as a national registry is in a unique position to promote, coordinate and facilitate registration at a national level (3,4). Establishing multiple and complementary enforcement mechanisms at a national level is considered the best strategy to ensure comprehensive trial registration (6). In Sri Lanka, there are no legal provisions that mandate registration of all trials conducted in the country with the SLCTR. This is an area that the SLCTR and the Ministry of Health need to address.

More transparency is needed not only in clinical trials, but in all types of clinical research. Several registries already accept registration of observational studies (9,11). One obvious advantage of this would be the availability of all clinical research data at a single point of access at a national level. The SLCTR does not currently register observational studies, and this is another area that needs further discussion. A common registration data set designed to meet the specific requirements of observational studies, similar to the current WHO-TRDS for clinical trials, would ensure uniformity of data across registries.

One of the biggest challenges for the SLCTR is improving awareness on clinical trial registration within the country. A survey on awareness conducted among the Sri Lankan scientific community has shown several areas for improvement (Ranawaka et al, unpublished data), in spite of the many initiatives undertaken by the SLCTR. Researchers need to be informed of the need for trial registration and the mechanisms available for it. Training of researchers, who are potential trial registrants, is also seen as a way of improving the quality of registration data (9). Educational campaigns, however, should not target only researchers. There is a huge information gap regarding clinical research among patients, caregivers and the general public, especially in developing countries. The importance of information being available in local languages has been previously stressed (7). More concerted efforts are clearly needed to improve awareness, and the SLCTR needs to continue working with other stakeholders in this regard.

Trial registration is not a national issue, but a global need that aims to ensure scientific validity of available evidence that guides clinical care worldwide. Even with the resource constraints, the SLCTR has striven to meet this global responsibility. It has worked closely with the WHO-ICTRP and with other partners in the Registry Network in improving trial registration and research transparency.

## Moving forward – together

When the SLCTR was first conceived, the immediate objective was to provide a platform for Sri Lankan researchers to register clinical trials in a national register. The SLCTR can be content that it has been able to achieve this. But clinical trial registration cannot exist in isolation; it is closely intertwined with conduct of all types of health research, research ethics and publication on one hand, and patient care on the other. And the SLCTR cannot exist in a vacuum as a mere repository of trial data. As a national body related to the conduct of clinical research, the broader goal of the SLCTR is to contribute meaningfully to the development of a research environment and a research culture that Sri Lanka can be proud of. This is a goal that is shared by all the stakeholders in this process – clinicians, researchers, ethics review committees, regulatory bodies and medical journal editors – and the SLCTR needs to continue formalising closer links with them to improve the research landscape in the country.

The establishment of the SLCTR has had a salutary effect on all facets related to the conduct of clinical research in the country, and the SLCTR and its partner stakeholders in clinical research need to harness this momentum – to disseminate knowledge, to build research capacity, and to ensure that clinical trials conducted in Sri Lanka meet the highest ethical and scientific standards. It is a long road ahead, and the establishment of the SLCTR was not a destination but a milestone, and the journey will be a lot easier if we share the burden.

### References


1. Ranawaka U K, Goonaratna C. Sri Lanka clinical trials registry. Ceylon Medical Journal 2007; 52: 117–119.
2. Ranawaka U K, Goonaratna C. Establishing the Sri Lanka Clinical Trials Registry. J Evid Based Med 2009; 2(1): 29–31.
3. Tharyan P. Prospective Registration of Clinical Trials in India: Strategies, Achievements & Challenges. J Evid Based Med 2009; 2(1): 19–28.
4. Grobler L, Siegfried N, Askie L, Hooft L, Tharyan P, Antes G. National and multinational prospective trial registers. Lancet 2008; 372: 1201–2.
5. Solaymani–Dodaran M, Ostovar A, Khalili D, Vasei M. Iranian Registry of Clinical Trials: path and challenges from conception to a World Health Organization primary register. J Evid Based Med 2009; 2(1): 32–5.
6. Ghersi D, Pang T. From Mexico to Mali: four years in the history of clinical trial registration. J Evid Based Med 2009; 2(1): 1–7.
7. Viergever RF, Ghersi D. The Quality of Registration of Clinical Trials. PLoS ONE 2011; 6(2): e14701. doi:10.1371/journal.pone.0014701
8. Sekeres M, Gold JL, Chan AW, Lexchin J, Moher D, Van Laethem ML, *et al*. Poor Reporting of Scientific Leadership Information in Clinical Trial Registers. PLoS ONE 2008; 3(2): e1610. doi:10.1371/journal.pone.0001610
9. Liu X, Li Y, Yu X, Feng J, Zhong X, Yang X, Li J. Assessment of registration quality of trials sponsored by China. J Evid Based Med 2009; 2(1): 8–18.
10. Zarin DA, Tse T, Ide NC. Trial Registration at ClinicalTrials.gov between May and October 2005. N Engl J Med 2005; 353: 2779–87.
11. Hasselblatt H, Dreier G, Antes G, Schumacher M. The German Clinical Trials Register: challenges and chances of implementing a bilingual registry. J Evid Based Med 2009; 2(1): 36–40.
12. Krleza-Jeric K, Chan AW, Dickersin K, Sim I, Grimshaw J, Gluud C. Principles for international registration of protocol information and results from human trials of health related interventions: Ottawa statement (part 1). BMJ 2005; 330: 956–8.
13. Haug C, Gotzsche PC, Schroeder TV. Registries and Registration of Clinical Trials. N Engl J Med 2005; 353: 2811–2.
14. Scherer M, Trelle S. Opinions on registering trial details: a survey of academic researchers; BMC Health Services Research 2008; 8: 18.