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*Review Article*

# Clinical trials landscape in Sri Lanka

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## ABSTRACT

Sri Lanka is an ideal destination for the global clinical trial industry due to its favorable national policies, growing economy, and rapid digitalization directly influencing the increasing global market size of clinical trials. Its comprehensive primary health care coverage, educated population, free standard of care, non-communicable disease burden equals to western countries, qualified medical practitioners, and a core of competent and committed clinical researchers combined with its population's proficiency in English also make this South Asian nation a potentially excellent regional clinical trials destination. Making an environment favorable to research partnership while guaranteeing the safe and ethical conduct of clinical trials has been a repetitive subject for conversation and discussion in the nation. A robust regulatory framework and ethical reviewing process have minimized legal loopholes ensuring the rights, safety, and well-being of trial participants that are protected. The Sri Lanka Clinical Trials Registry is a non-revenue driven registry and it can be considered a key stimulus to the ongoing discussions on clinical trials in Sri Lanka. Moreover, the adoption of new technology in clinical research and the rise of the pharmaceutical industry encourages and creates opportunities for more clinical trials to be conducted in Sri Lanka which, in turn, influences the growth of the industry.

**Keywords:** Contract research organization, South Asia, Site management organization, GCP, WHO-ICTRP

## INTRODUCTION

Sri Lanka's medical infrastructure consists of government-funded hospitals which can serve as ideal sites for multi-center clinical trials. Furthermore, well-defined primary, secondary, and tertiary care hospitals and specialty centers, including two National Hospitals, 20 teaching hospitals, and 25 district general hospitals, are available. There are many medical laboratories accredited both locally and internationally and are accessible for all clinical testing. Free healthcare and the consequent large volume of patients at government hospitals are opportunistic when considering Sri Lanka for conducting pivotal clinical trials. Our local medical professionals are highly skilled and well experienced possessing qualifications recognized internationally. Their exposure to clinical research having gone through ICH-GCP training and 4–6 years of professional experience is an added advantage. Sri Lanka has impressive healthcare indices where we have successfully eradicated Polio and Malaria and controlled infections such as AIDS (adult prevalence < 0.1%),[1] SARS, and H1N1. In addition, Sri Lanka's management of the COVID-19 pandemic was recently lauded by the WHO Director-General. The country's effective response to COVID-19 (94.8% recovery rate and 0.6% death rate) is attributed to its historically strong public health system. Sri Lanka was also ranked ninth on the Global Response to Infectious Diseases index for managing the recent COVID-19 outbreak. Sri Lanka has an average of 92.5% literacy

rate,[2] the highest in the South Asian region. The high literacy rate vastly enables patients' comprehension of the consent process, leading to proper recruitment and effective follow-ups. Digitalization of biomedical research increases the size of the global clinical trial market, and with Sri Lanka's level of infrastructure support in information technology (61.5/100-person internet penetration[2]), we have created our pace and need in the global industry.

Sri Lanka has a robust regulatory framework administrated by the National Medicines Regulatory Authority (NMRA) in compliance with GCP standards set by the International Council for Harmonization (ICH) and the US Food and Drug Administration standards. The NMRA's guidelines published on October 15, 2019, provide a comprehensive guidance to assist clinicians, scientists, sponsors, and research organizations to become familiar with existing procedures and requirements for the conduct of clinical trials in Sri Lanka. NMRA provides regulatory approval, relevant import licenses, and certificates required for the clinical trials. The NMRA Act, No. 5 of 2015 and regulations made thereafter have strengthened the legal framework for clinical trials and are aligned with ICH-GCP guidelines. The legislation secures Contract Research organizations (CROs) and clinicians engaged in clinical trials and the trial participants from possible injuries and entrusting their legal rights in trial participation.[3]

To receive approval for a clinical trial, ethical clearance from an Ethics Review Committees (ERC) recognized by the NMRA is required. The ERC of the University of Colombo Faculty of Medicine was established in 1981 and was Sri Lanka's first institutional ERC. The Clinical trial evaluation committee has recognized and accredited nine ERCs. The rise in the quantity of ERCs established and the quality of their ability to review projects was partly determined by an increase in international collaborative research conducted in Sri Lanka and the desire to create robust research governance of the kind needed to attract trials in the future. In 2007, the guidelines for developing standard operating procedures for ERCs that review biomedical research proposals in Sri Lanka were published by the Forum of ERCs in Sri Lanka (FERCSL).[4] This has provided the uniform standard operating procedures for ERCs in Sri Lanka.

The Sri Lanka Clinical Trials Registry (SLCTR) is a central repository of key information about Registry for clinical trials involving human subjects, conducted in Sri Lanka or overseas. All clinical trials to be conducted in Sri Lanka are required to be registered in SLCTR. It is a non-revenue driven registry, and it can be considered a key stimulus to the ongoing discussions on clinical trials among Sri Lankan researchers, clinicians, professional associations, administrators, and health care planners. The SLCTR was recognized as a primary registry of the Registry Network of WHO-ICTRP in March 2008, being the fourth to join the network, and is the first fully functioning clinical trial registry in South Asia.[5] It also remains as one of the registries from a resource-limited setting.

Sri Lanka was recently identified as a high middle-income economy. As a developing country with sudden urbanization and lifestyle changes, non-communicable diseases (NCDs) are a challenge to the national economy and public health. According to the Global Burden of Disease Study in 2010, the highest-ranking for the causes of number of years of life lost (YLLs) in Sri Lanka is premature death caused by ischemic heart disease, self-harm, cerebrovascular diseases, strokes, and diabetes.[6] More than three-quarters of all deaths are due to NCDs, and nearly 1 in 5 people die prematurely from NCDs.[7] According to the most recent STEPS survey for NCDs, 1 out of 4 people have raised blood pressure, and a third are overweight. Recent statistics also show that 1 in 12 adults suffer from diabetes, which give a total of 1.16 million diabetic adults nationally.[7] With the modern lifestyle and sudden urbanization taking over, mental health disorders have become a major socio-economic challenge too. As per the global health estimates of the WHO in 2015, there were approximately 802,321 reported cases of depression in Sri Lanka. The prevalence of depressive disorders in Sri Lanka is 4.1%, which is not notably different from the Southeast Asia region prevalence (4.4%).[8] Sri Lanka being a tropical island, the climate is frequently affected by mosquito-borne diseases. Although Sri Lanka has successfully eradicated malaria, dengue fever makes seasonal outbreaks causing a considerable number of deaths. In 2019, 96,903 dengue cases and 90 clinically confirmed dengue deaths have been reported from all parts of the country.[9]

According to SLCTR statistics, over the past 10 years, they have received over 324 applications for clinical trials, out of which 16 were multi-country studies. In the past, most of the clinical trials included adults only, and trials to be conducted on child participants under 12 years were comparatively lower. The SLCTR statistics also showed that out of 210 trials, 164 included male and female participants, whereas 43 trials were conducted on females only and three trials on males only.[10] In the past 10 years, diabetes (including gestation) made up for more than 14% of registered trials and was the most researched therapeutic area. This was followed by pregnancy and its outcomes (12.4%) and infections/infestations (7.14%). The percentage of clinical trials for metabolic diseases (1.9%) was the lowest.[10]

Over one-third of the registered trials (37.1%) had completed recruitment according to SLCTR statistics over the past 10 years.[10] Most of the principal investigators were affiliated to either a local or foreign university, while 19% were affiliated to a hospital and 6.2% were affiliated to institutions of the Ministry of Health. Only 1.4% of trials were directly

affiliated with the pharmaceutical industry.[10] Sri Lanka has a rich history of traditional medicine systems consisting of Ayurvedic medicine, and thus, a considerable number of clinical trials are based on herbal pharmaceuticals. The majority of the registered trials were conducted only in Sri Lanka and 9.5% of registered trials were multi-country collaborative trials conducted in Sri Lanka. Investigator-sponsored clinical trials (86.2%) were significantly higher than industry-sponsored trials (13.8%).[10] SLCTR statistics over the past 10 years imply that the clinical trial industry in Sri Lanka is opportunistic in terms of growth within South Asia and this is yet to be identified and addressed.

Sri Lanka recruited 2100 participants for a dengue vaccine trial that was industry-sponsored and successfully achieved the recruitment target within a short-time period. The trial was conducted in collaboration with the Ministry of Health and the Epidemiology Unit, and the primary efficacy results were published in the New England Journal of Medicine (NEJM). An investigator-sponsored multi-country trial that aimed at testing the theory that low doses of three medications could achieve better blood pressure control for patients with mild-to-moderate hypertension was conducted in Sri Lanka. The results were published in the Journal of the American Medical Association (JAMA).

Newly implemented national policies inviting new industries to the country create a promising future for the clinical trial industry in Sri Lanka. Subsidiary companies such site management organizations (SMOs) bring benefits such as large patient numbers, centralized site coordination (e.g., streamline contracting and regulatory documents), simplified ethics applications, commitment to quality through rigorous quality oversight of all sites, project management of the on-site study coordinator resources (includes KPI-driven management and coaching to ensure delivery to recruitment targets), an intimate knowledge of the strengths and weaknesses of the clinical trial process within each site and being well placed to make thorough assessments of their suitability for a particular study.

## CONCLUSION

In summary, Sri Lanka is an ideal destination for the global clinical trial industry due to our favorable national policies, growing economy, and rapid digitalization directly influencing the increasing global market size of clinical trials. Its comprehensive primary health care coverage, educated population, free standard of care, non-communicable disease burden equals to western countries, qualified medical practitioners, and a core of competent and committed clinical researchers combined with its population's proficiency in English also make this South Asian nation a potentially excellent regional clinical trials destination. Making an environment favorable to research partnership while guaranteeing the safe and ethical conduct of clinical trials has been a repetitive subject for conversation and discussion in the nation. A robust regulatory framework and ethical reviewing process have minimized legal loopholes ensuring the rights, safety, and well-being of trial participants that are protected. Moreover, the adoption of new technology in clinical research and the rise of the pharmaceutical industry encourages and creates opportunities for more clinical trials to be conducted in Sri Lanka which, in turn, influences the growth of the industry.

### Declaration of patient consent

Patient's consent not required as there are no patients in this study.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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