

## Session 1: 16:10 – 16:25

### Setting up clinical trial in resource-limited contexts: challenges and current status (Thailand)



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#### Short CV

**Professor Kulkanya Chokephaibulkit** graduated and trained in Pediatrics at the Faculty of Medicine Siriraj Hospital.

She then specialized in pediatrics Infectious diseases and epidemiology from the Cedars-Sinai Medical Center, the University of Tennessee and at Emory University, respectively.

She is currently the Director of Siriraj Institute of Clinical Research (SiCRES), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. She is also Executive Board of national Vaccine Institute of Thailand, Member of Member of Expert Panel of the Adverse Event Following Immunization (AEFI), Ministry of Public Health, Thailand, and Member of the Subcommittee of Board of National Immunization, Ministry of Public Health, Thailand.

She is also Clinical Research Site Principal Investigator of International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) supported by NIH.

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#### Abstract

Clinical research in resource-limited settings (RLS) is challenging for many reasons.

The regulatory requirement for investigational products importation can be complicated and lengthy. The ethical review process in RLS can be relatively slower in than the more developed countries. The infrastructures required to support clinical trials—e.g., preparation of trial products, protocols and case report forms, data management system, statistical support, monitoring, and reporting— are not readily available.

Facilities for laboratory testing are insufficient and rarely accredited to meet the regulatory requirement. The quality management system may not be strong. Finally, the high routine workload with patient-care services competing priority may distract the interest of expert clinicians from conducting clinical research.

Research infrastructure and capacity in RLS should be established and sustained. A strong political support, effective collaboration, adequate expertise and resources, and clear guidance are needed to overcome these barriers. This requires investments in training and career structures to develop a diverse pool of country's highly skilled research workforce.

Clinical research in Thailand has been highly supported recently, but many hurdles remain. The opportunity is the large diversified patient population available that can potentially be the subjects. Other strengths include cost-effectiveness in conducting trials, well-recognized medical schools, a high incidence of tropical diseases, and access to state-of-the-art medical equipment and facilities. The challenges remain on the insufficient skillful staff and routine working system to support the research work. SiCRES is the Faculty's clinical research center and beyond. The experience of setting-up SiCRES, we found collaboration and engagement of public and private partners are essential parts of how we work. We collaborate with governments, Ministry of Public Health, Ministry of Higher Education, Science, Research and Innovation and local partners to build capacity, strengthen research services. We optimize clinical research by learning from each other's .