

EDCTP Portfolio

Knowledge Management



1.1 Pan African Clinical Trial Registry (PACTR)

EDCTP Project Coordinator:	Jimmy Volmink (Medical Research Council South Africa (MRC), South Africa)
EDCTP Call Title:	Coordination and networking of research activities in Africa
EDCTP Project Title:	Pan African Clinical Trials Registry
EDCTP Project Code:	CT.2004.70100.001
EDCTP Project Start Date:	10 June 2006
EDCTP Project End Date:	31 December 2014
Collaborators:	<ul style="list-style-type: none"> • Tamara Kredon (South Africa) • Elizabeth Pienaar (South Africa)
Objectives:	To increase the registration of clinical trials in Africa
Status:	Ongoing
Results and Outcomes:	<ol style="list-style-type: none"> 1. PACTR has received positive support and increased registration through its evolution which resulted from a request from the World Health Organization (WHO) and the African Vaccine Regulatory Forum for registration of all randomised controlled and controlled clinical trials regardless of disease type conducted in Africa, thus the HIV/AIDS, Tuberculosis and Malaria Clinical Trials Registry was transformed to the Pan African Clinical Trials Registry (PACTR) in June 2008 2. In September 2009 PACTR was officially recognised as a WHO Primary Registry 3. The web-based portal hosting www.pactr.org currently has an online registration facility that meets the standards required by the WHO International Clinical Trials Platform (ICTRP) and its status as a Primary Registry was renewed in 2010 and in 2011 4. By January 2010 the Registry applications had doubled since the official launch and by December 2010, the Registry had received 67 applications, of which 36 eligible trials were registered 5. By April 2011 application submissions increased to 96 of which 46 were registered, 41 were denied (31 were denied because application was submitted while the trials had already started) and 9 were pending review 6. In August 2011 the Geographic Information Systems (GIS) component was launched on the database portal to facilitate the visual presentation of trial locations on a map of Africa 7. In March 2012 a flagging system was introduced to mark trials that are retrospectively registered. This enables trial applications previously denied registry numbers due to the timing of their application to be registered. In addition the remit of the Registry has been expanded to accept phase 0-4 trials 8. By December 2012, 220 applications had been submitted to the Registry of which 141 were registered, 47 were denied or in-eligible and 36 are pending review
Publications:	<ol style="list-style-type: none"> 1. Abrams A, Siegfried N, Geldenhuys H. 2011. Adolescent Trial Experiences in a vaccine trial: a pilot project. <i>South African Medical Journal</i> 2011; 101:884-886 2. Abrams A, Opiyo N, Crawley S, Cotton M, Wiysonge C, Okebe J. Supporting registration of child-focused clinical trials in Africa: The Child Strategy project. <i>S Afr Med J</i> 2011; 101(11):804 3. Abrams A, Siegfried N. Growing Everyday: The Pan African Clinical Trials Registry. <i>Journal of Evidence-Based Medicine</i>

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6. Abrams A, Siegfried N. The Pan African Clinical Trials Registry: year one data analysis of the only African member of the World Health Organization Network of Primary Registries. *The Journal of Evidence-Based Medicine*, 2010, 3. Pp.195 – 200
7. Baleta A. African Trials Registry Launches Child Strategy. *The Lancet*, 2010, 375. pp. 1423
8. Abrams A, Siegfried N. A Pan-African Clinical Trials Registry for the specific needs of trialists on the continent. *South African Medical Journal*, 2010, 100(5): 294 -95
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