



Building a healthy nation through research

Pan African Clinical Trials Registry



Tamara Kredo

South African Cochrane Centre

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Presentation overview

- Introduction
- Clinical Trial Registration
- The Pan African Clinical Trials Registry (www.pactr.org)



Acknowledgements

- Trial registrants
- The European and Developing Countries Clinical Trials Partnership (EDCTP)
- The South African Cochrane Centre, SAMRC



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Why do research?



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“... it is usually a body of evidence, consisting of many studies that changes medical practice. When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers, and experts who write practice guidelines . . . If all trials are registered in a public repository at their inception, every trial’s existence is part of the public record, and the many stakeholders in clinical trial research can explore the full range of clinical evidence”

-ICMJE statement 2004 (JAMA, 15 September 2004 – Vol 292 No. 11)

AllTrials campaign



THE PROBLEM

More than 50% of clinical trials have not reported results.

Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for good medicine, and trials needlessly repeated.

WHAT CAN YOU DO?

- Ask your organisation to join the campaign
- Write a feature, blog post, editorial, or tell your members in your organisation's newsletter
- Ask your friends, family, and colleagues to sign up
- Donate to the campaign
- Get involved in other ways via www.alltrials.net

All Trials Registered | All Results Reported



www.alltrials.net

+ AllTrials



What is a clinical trials register?

A database in which key administrative and scientific information about planned, ongoing and completed trials, sufficient to identify that trial's existence, are stored

The 2004 Ministerial Summit on Health Research called on the WHO to establish:

“a network of international clinical trial registers to ensure a single point of access and the unambiguous identification of trials”



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What is the process you follow to register trials?



Benefits to Registering

- Reduce publication bias
- Fulfills ethical obligation to participants
- Ensure transparency
- Enhance public trust in the conduct of clinical research
- Increase enrollment in research trials
- Reduce duplication of research and limited resources
- Feeds data to a central WHO database

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International Clinical Trials Registry Platform (ICTRP)

[WHO](#) > [Programmes and projects](#)

Welcome to the WHO International Clinical Trials Registry Platform

The mission of the WHO Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.

The registration of all interventional trials is a scientific, ethical and moral responsibility.

What is a clinical trial?

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc

Functions

[The Register Network](#)[The International Search Portal](#)

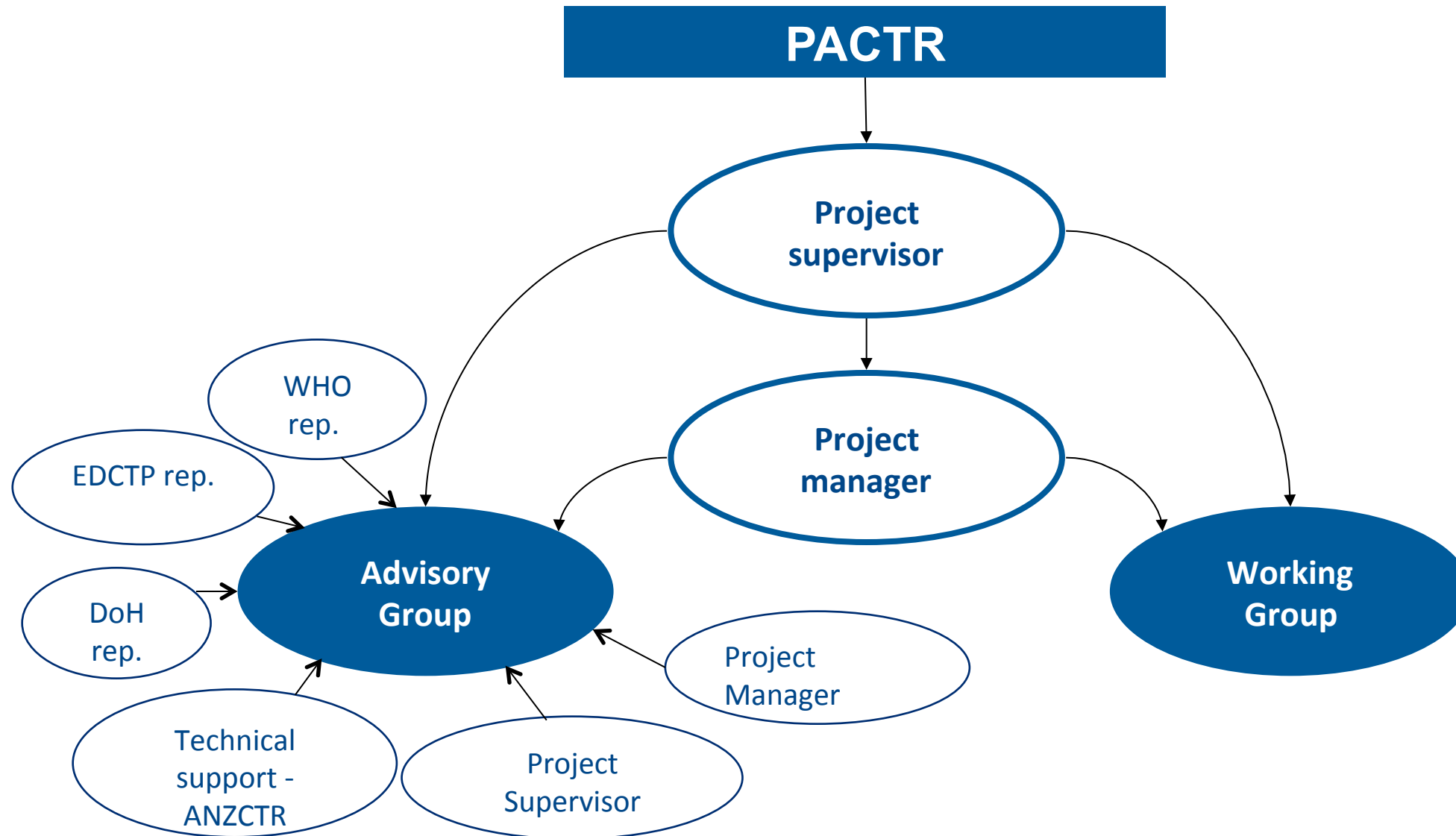
World Health Organization

INTERNATIONAL CLINICAL TRIALS
REGISTRY PLATFORM
SEARCH PORTAL

[Search for trials](#)[The Register Network](#)[List of Registers](#)[Frequently Asked Questions](#)



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Home

- Why register a trial
- Benefits of registering a trial
- Frequently asked questions
- How to register a trial
- Links to other information
- Governance
- Terms and Conditions



The European and
Developing Countries
Clinical Trials
Partnership



The South
African
Cochrane
Centre



South
African
Medical
Research
Council

Home

The Pan African Clinical Trials Registry (PACTR) is a regional register of clinical trials conducted in Africa. The registry is an African initiative serving the needs of Africans. It provides an open-access platform where clinical trials can be registered free of charge. The PACTR aims to increase clinical trial registration in Africa by developing awareness of the need to register trials and supporting trialists during registration.

Download information for Partner Registry Application here.
Due June 15, 2014

In addition, PACTR provides a searchable, electronic database of planned trials and trials currently in progress. Those wishing to search the database of trials, can do so from the homepage, by clicking on the "search" link. There is no need to register on the site if you simply want to search the database.

The PACTR is unique in recognising that African trialists face additional challenges in trial registration and seeks to provide feasible ways of overcoming these. For example, a common problem for individuals living in sub-Saharan Africa is limited, unreliable and costly internet access. With this in mind, the registry provides alternative means of trial registration for registrants who do not have reliable access to the internet. Trials may be registered manually by email, postal mail or facsimile correspondence and trial registration is free.

Partners

Start-up funding for PACTR was provided through a grant from the European and Developing Countries Clinical Trials Partnership (EDCTP) and is based at The South African Cochrane Centre (SACC), which is located at the South African Medical Research Council (MRC).

The registry is working in collaboration with **The Cochrane Infectious Diseases Group (CIDG)**, (based at the Liverpool School of Tropical Medicine), the **Cochrane HIV/AIDS Group** (based at the University of San Francisco and the SACC), and the World Health Organization (WHO).

Please note: The ATM Clinical Trials Registry has been expanded to include all health conditions and renamed the **Pan African Clinical Trials Registry (PACTR)**.

Search

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Pan African Clinical Trials Registry

South African Medical Research Council, South African Cochrane Centre
 PO Box 19070, Tygerberg, 7505, South Africa
 Telephone: +27 21 938 0506 / +27 21 938 0834 Fax: +27 21 938 0836
 Email: pactradmin@mrc.ac.za Website: www.pactr.org

Trial no.: <small>WHO</small> PACTR201202000354245	Date registered: <small>WHO</small> 2012/02/01
Trial Status:	Registered in accordance with WHO and ICMJE standards
TRIAL DESCRIPTION	
Public title <small>WHO</small>	Bridging Trial of Bivalent Killed Oral Cholera Vaccine in Ethiopia
Official scientific title <small>WHO</small>	A RANDOMIZED, DOUBLE-BLIND, CONTROLLED TRIAL TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF KILLED BIVALENT (O1 AND O139) WHOLE-CELL BASED ORAL CHOLERA VACCINE (SHANCHOL®) IN HEALTHY INDIVIDUALS IN ETHIOPIA
Brief summary describing the background and objectives of the trial	To confirm the safety and determine the immune response to the two dose-regimen of whole cell oral cholera vaccine (Shanchol®) among healthy adults and children in Ethiopia.
Type of trial	RCT
Acronym (If the trial has an acronym then please provide)	
Disease(s) or condition(s) being studied <small>WHO</small>	Cholera
Purpose of the trial	Prevention
Anticipated trial start date <small>WHO</small>	2012-03-12
Actual trial start date <small>WHO</small>	
Anticipated date of last follow up <small>WHO</small>	2012-09-10
Actual date of last follow up <small>WHO</small>	
Anticipated target sample size (number of participants) <small>WHO</small>	216



Networking Resource

- PACTR provides users with the contact details for those involved in the research, allowing for networking through the registry
- PACTR provides researchers in a particular field a resource to search for funders who supported topics in their area of interest
- PACTR provides a resource for potential participants to find specialists researching their condition, and an opportunity to be involved with the trial



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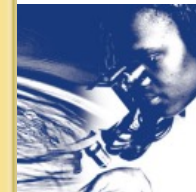
SPONSORS ^{WHO}						
Sponsor level	Name	Street address	City	Postal code	Country	Nature of sponsor
Primary Sponsor	National Liver Institute, Menoufiya University	Yassin Abdelghafar	Shebeen El-Kom, Menoufiya	32511	Egypt	Hospital



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COLLABORATORS

Name	Street address	City	Postal code	Country
Ayman Alsebaey Alghoraieb	National Liver Institute, Menoufiya Univ D Yassin Abdelghafar St,	Shebben El- Kom, Menoufiya	32511	Egypt



CONTACT PEOPLE

Role	Name	Email	Phone	Fax
Public Enquiries <small>WHO</small>	Dr Ayman Alsebaey Alghoraieb	aymanalsebaey@yahoo.com	+201003751248	+20482234586

Street address	City	Postal code	Country	Position / Affiliation
Nat Liver Institute, Univ Manoufiya	Shebeen El-Kom	32511	Egypt	Lecturer of Hepatology, National Liver Institute, Menoufiya University, Shebeen El-Kom, Egypt

Role	Name	Email	Phone	Fax
Principal Investigator <small>WHO</small>	Dr Ayman Alsebaey	aymanalsebaey@yahoo.com	+201003751248	+20482234586

Street address	City	Postal code	Country	Position / Affiliation
Nat Liver Institue, Menoufiya Univ, Dr Yassin Abdelghafar St	Shebeen El-Kom, Menoufiya	32511	Egypt	Lecturer of Hepatology, National Liver Institute, Menoufiya University, Shebeen El-Kom, Egypt

Role	Name	Email	Phone	Fax
Scientific Enquiries <small>WHO</small>	Dr Ayman Alsebaey Alghoraieb	aymanalsebaey@yahoo.com	+201003751248	+20482234586

Street address	City	Postal code	Country	Position / Affiliation
Nat Liver Institute, Menoufiya Univ, Dr Yassin Abdelghafar street	Shebeen El-Kom, Menoufigy	32511	Egypt	Lecturer of Hepatology, National Liver Institute, Menoufiya University, Shebeen El-Kom, Egypt



Regional overview

- Facilitates understanding of regional research patterns, i.e., where research is over-done and participants are spread thin vs. places where research has not been conducted
- Enable the identification of research gaps for future studies
- Facilitate the investigation of the scope, quality and funding patterns of African trials



Type of intervention

Search

Title: malaria

Type: Treatment

Disease: * All *

Country: * All *

Site Type: * All *

City: * All *

Status: * All *

Results

4 ACT for uncomplicated malaria in Africa

Centre Muraz

Hospital Albert Schweitzer,

Institute for Tropical Diseases Research

Manhica Health Research Centre

Mbarara University of Science and Technology

The National Malaria Control Programme

The Tropical Diseases Research Centre

Uganda Malaria Surveillance Project

A study comparing the efficacy of clindamycin

Ahero sub-District Hospital

An RCT to measure the impact of retreatment

Centre de Sante Lisungi

Kazo Health centre IV

Antimalarial Dose Justification and Tolerability

Chikhwawa District Hospital (CDH)

ARCO? Vs COARTEM? for treating uncomplicated malaria

University of Calabar Teaching Hospital

Efficacy and safety of artemether lumefantrine

Karonga District Hospital

Kawale Health Centre

Machinga District Hospital

Mangochi District Hospital

Nkhotakota District Hospital

Rumphi District Hospital

Efficacy, Safety and Pharmacokinetics of

Centre National de Recherche et de Formation

Department of Paediatrics, University of

Ecole de Sante publique/Universite de

HOMEL (Hopital de la Mere et de l'Enfant)

Service de Pediatrie, CHU-Tokoin

Unite de Recherche Clinique de Nanoro

Map

Zoom in Zoom out Print

Trial info

Randomised contr...

Title: Randomised control trial of a single dose oral regimen of Artemisinin Naphthoquine versus Artemether lumefantrine for uncomplicated malaria in Children

Acronym:

Disease: Malaria

Location: Ikot Otu Abasi

Country: Nigeria

City: Akpabuyo

Creation Date: 09-APR-12

Actual Start Date:

Sample Size:

Recruitment Type:

Recruitment Status: Not yet recruiting

Type of intervention: Treatment

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1000 km

1000 mi

Map data ©2014 Google, INEGI

Latitude: 08°04'05"N Longitude: 05°03'30"E



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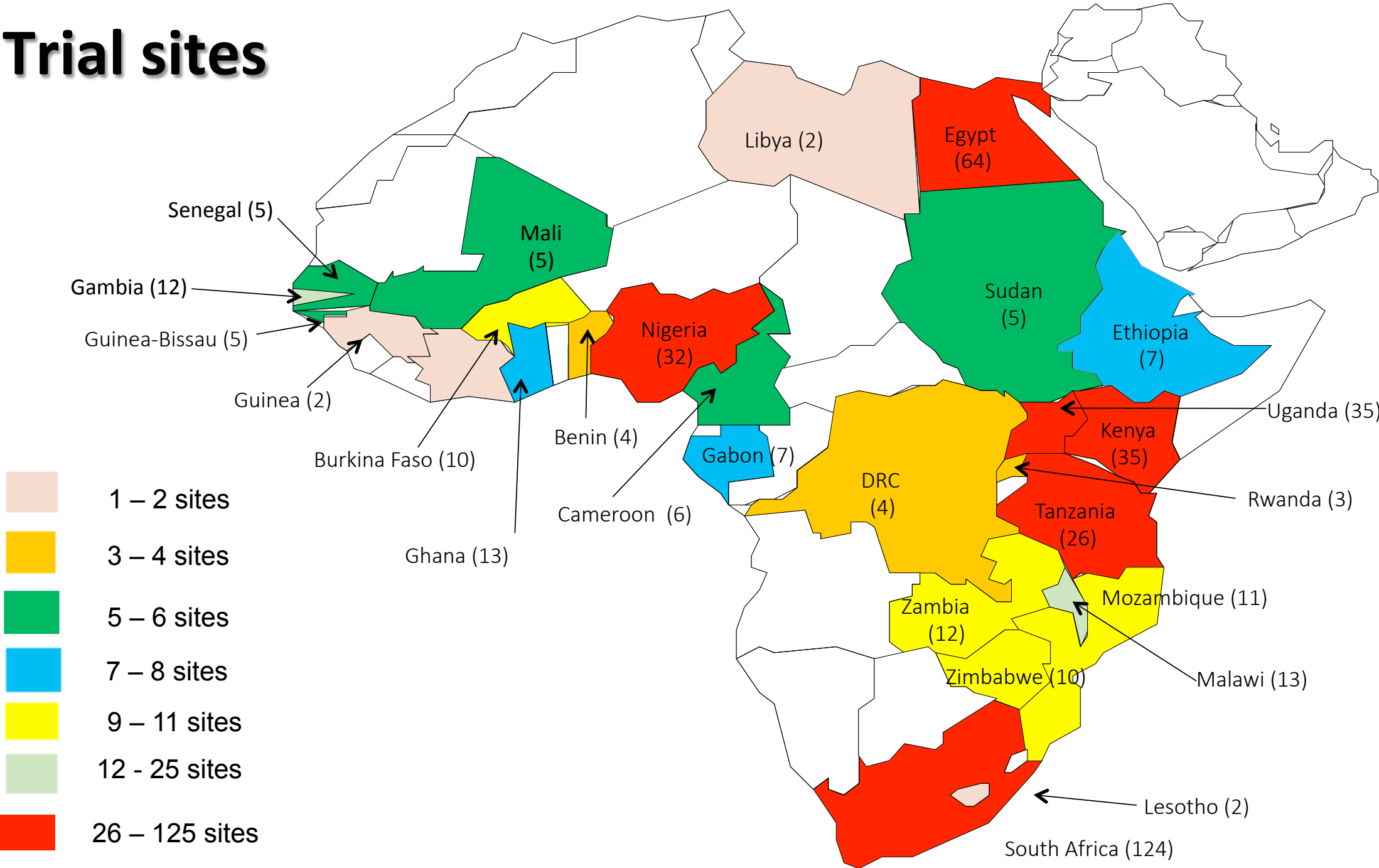


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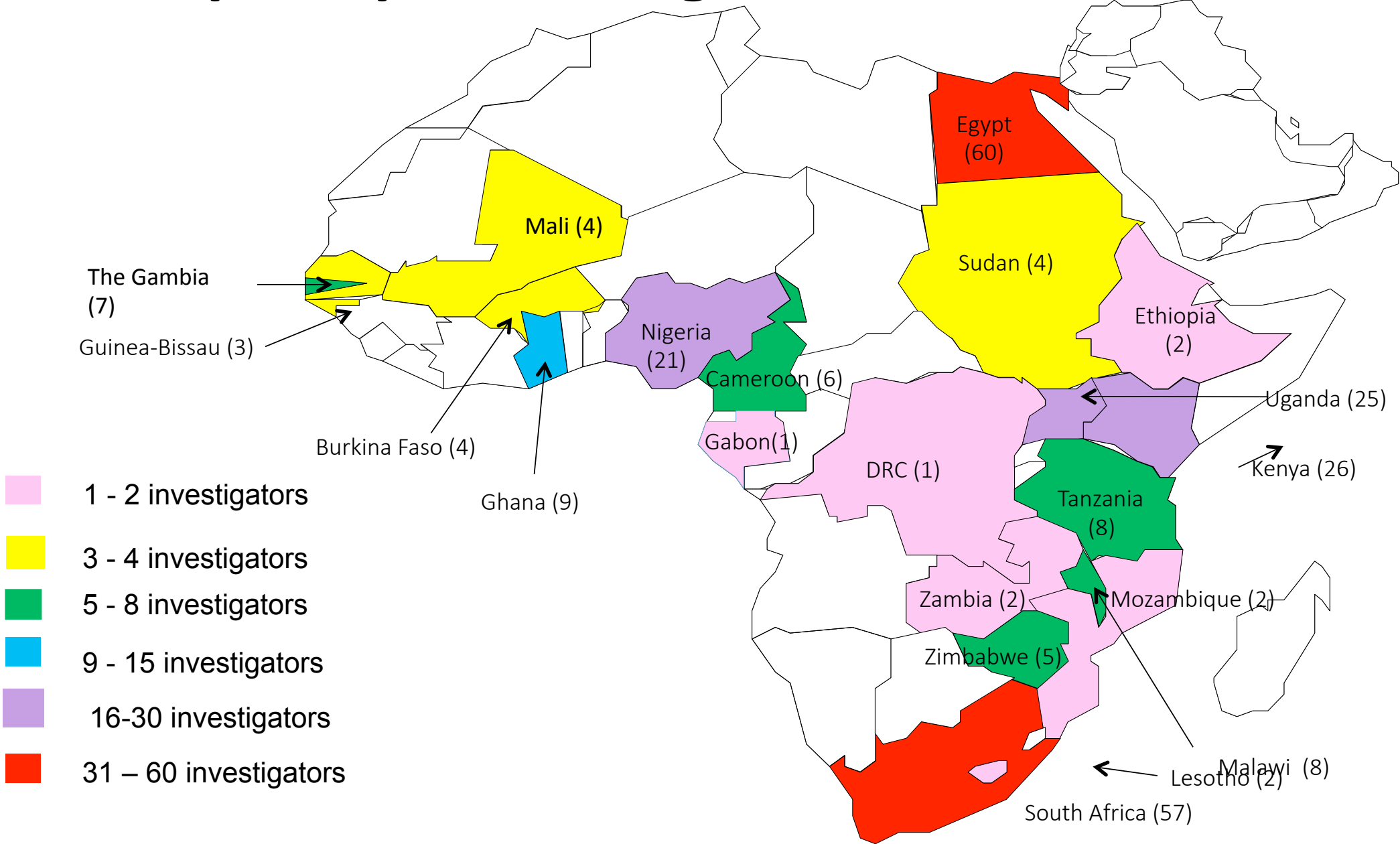
What is in www.pactr.org?

Disease Type	Total
HIV/AIDS	43
Malaria	38
TB	22
Co-morbid (more than one condition)	28
Other – Non communicable	93
Other - Communicable	11
Maternal and child health	63
All Diseases	1
Trial conduct	1

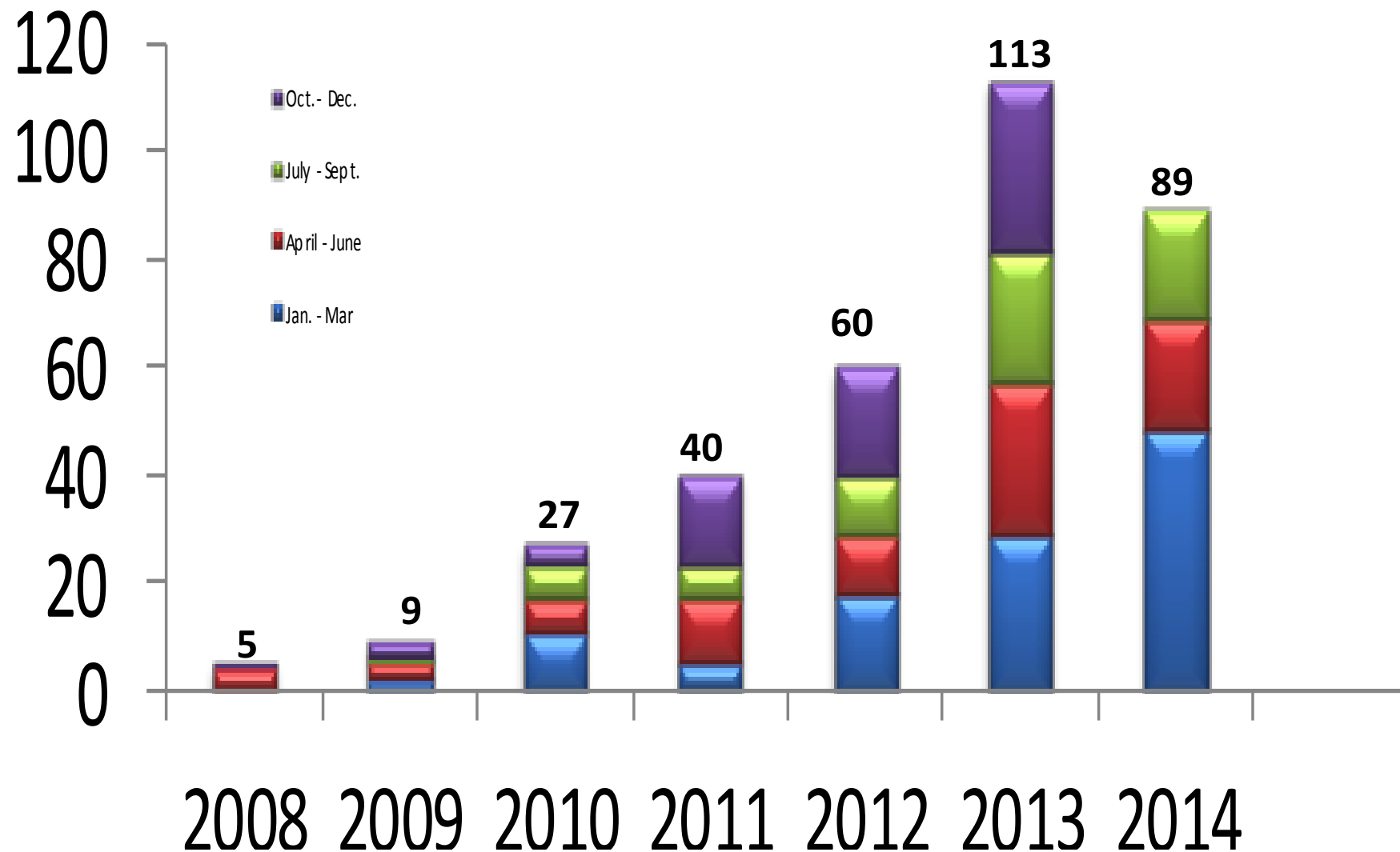
Trial sites



African principle investigators



Trials registered on www.pactr.org





The past five years

- The development of our GIS Mapping Component
 - Fully interactive, real-time GIS map that visually displays registered trial sites
- Maintained WHO primary status
- WHO Pan African Clinical Trials Alliance (PACTA) involvement
- Continued networking with AVAREF, COHRED, and SADC



Selected Publications

- Abrams, A. and Siegfried, N. (2011), Growing Everyday: The Pan African Clinical Trials Registry. *Journal of Evidence-Based Medicine*, 4: 172–178.
- Abrams A, Opiyo N, Crawley S, Cotton M, Wiysonge C, Okebe J. (2011). Supporting registration of child-focused clinical trials in Africa: The Child Strategy project. Editorial. *SAMJ* 101(11):804



Challenges

- Limited staff
- Single language of access
- Despite efforts, awareness of need to register still limited
- Finding grant calls that encompass the type of work www.pactr.org does



Future Developments

- Creating a discussion forum on the PACTR portal
- Providing users with downloadable data (ppt format)
- Increase the resources available through the portal, including webcasts, networking options and links to other sites
- Providing links to published documents related to specific trials
- Partnering with African countries that want to provide data to WHO but have not developed primary registries



Future Objectives

- Ensure all trials are identified and trial information made widely available in an open-access repository
- Assist in harmonising the efforts to regulate, register and review clinical trials on the African continent
- Develop continental-wide awareness
- Maintain primary registry status
- Continue networking efforts with other registries
- Secure future funding to ensure long-term sustainability



Contact Information

To register your trial or for more information please contact us at:

Website: www.pactr.org

Email: pactradmin@mrc.ac.za or epienaar@mrc.ac.za

Telephone: +27 21 938 0835

Fax: +27 21 938 0836



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How can www.pactr.org strengthen health capacity?

- ▶ www.pactr.org provides a resource for stakeholders
 - Policy Makers, Regulators and Ethics Review Boards
 - Healthcare professionals (clinicians, nurses, etc.) and researchers
 - Healthcare research funders and sponsors
 - Healthcare consumers
- ▶ Supports harmonization and collaboration between nations
- ▶ Raises regional awareness
- ▶ Increasing the profile of African clinical trial capacity