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E D C T P



Building a healthy nation through research

Pan African Clinical Trials Registry (PACTR)

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Acknowledgements

- **The European and Developing Countries Clinical Trials Partnership (EDCTP)**
- **Trial registrants**
- **WHO/AVAREF**



*European and Developing Countries
Clinical Trials Partnership*



What is a clinical trials register?

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



Why register clinical trials?

Background:

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”



So, why register?

- In 2005 the above call was
 - endorsed by the 58th World Health Assembly
 - supported by the International Committee of Medical Journal Editors (ICMJE)
- In 2007 the ICMJE updated their statement:
 - Only trials registered on WHO-endorsed primary registers would be published



Benefits to Registering

- **Reduce publication bias**
- **Fulfill researchers ethical obligation to research participants**
- **Ensure transparency and enhance public trust in the conduct of clinical research**
- **Increase participant enrollment in research trials**
- **Reduce duplication of research and limited resources**



The WHO International Clinical Trial Registry Platform (ICTRP)

- The WHO ICTRP is not a clinical trials registry
- WHO ICTRP
 - is a platform facilitating prospective registration of a minimum 20-item data set
 - harmonises and standardises
 - provides a searchable portal
- This platform's goals have guided the development of PACTR



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International Clinical Trials Registry Platform (ICTRP)

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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](#)



INTERNATIONAL CLINICAL TRIALS
REGISTRY PLATFORM
SEARCH PORTAL

[Search for trials](#)



[The Register Network](#)



[List of Registers](#)

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Why PACTR?

- **PACTR's WHO-endorsed primary registry status allows researchers in Africa to register their trials with the registry of choice for the African region**
- **The PACTR seeks to provide feasible ways of overcoming obstacles specific to African trialists**
- **Registration is free, and information on registered trials is easy to search and free to access**



2006/2007: The AIDS, TB and Malaria (ATM) Clinical Trials registry project is established



May 2007: ATM Registry launched and operational



February 2008: The ATM Registry portal site went live



May 2008: The South African National Clinical Trials Registry (SANCTR) agrees to share data with the ATM Registry



June 2009: Transition to the PACTR as remit expands



July 2009: The PACTR awarded WHO Primary Registry status



The PACT Registry

- Provides a source of reliable information on the efficacy and safety of prevention and treatment measures
- Identifies research gaps that should be addressed in future trials
- Provides a ‘laboratory’ for studying the scope, quality and funding patterns of trials
- Is a source of information for potential trial participants



World Health Organization
Regional Office for Africa

African Vaccines
Regulatory Forum
(AVAREF)



World Health
Organization



LIVERPOOL
SCHOOL OF
TROPICAL
MEDICINE



The Cochrane HIV/AIDS Group



The South African
Cochrane Centre

AFRICA CLINICAL
TRIALS PORTAL

CONSOLIDATED
REPORTING OF TRIALS
GROUP (CONSORT)



PACT
Registry

ANZCTR
Australian New Zealand Clinical Trials Registry



E D C T P

European and Developing Countries
Clinical Trials Partnership

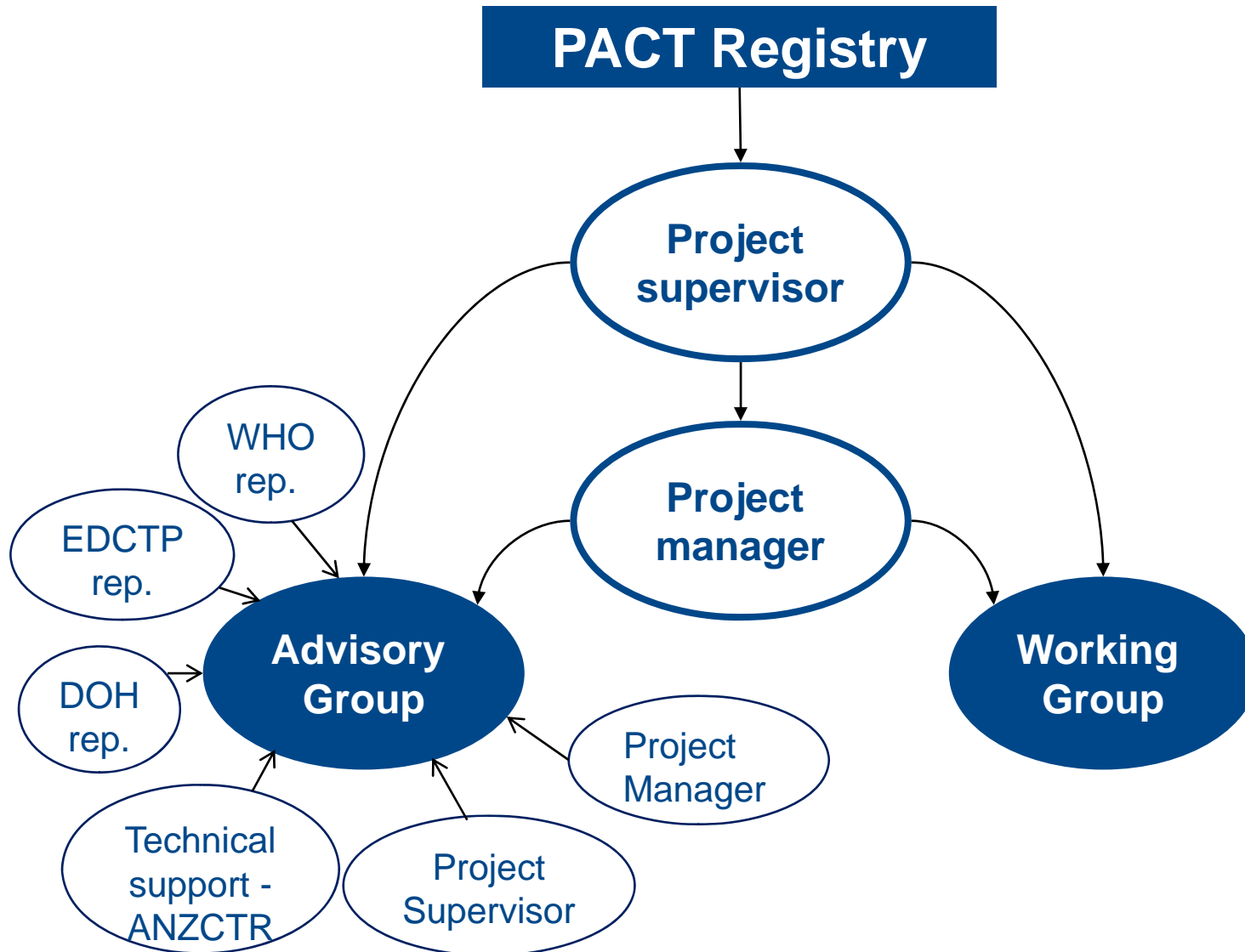
ClinicalTrials.gov
A service of the U.S. National Institutes of Health



health

Department:
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REPUBLIC OF SOUTH AFRICA

South African National Clinical Trial Register





Pan African Clinical Trials Registry

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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 a platform where clinical trials can be registered prospectively. In addition, it also provides a searchable, electronic database of planned trials and trials currently in progress. 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

The PACTR is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) and the primary partners are:

1. [The South African Cochrane Centre \(SACC\)](#), based at the South African Medical Research Council (MRC)
2. [The Cochrane Infectious Diseases Group \(CIDG\)](#), based at the Liverpool School of Tropical Medicine.

The registry is working in close collaboration with 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)**.





How to Register a Trial?

Registration can occur online, by email, postal mail or facsimile. The following information is required to begin registering a trial:

- **Title of trial**
- **Trial acronym**
- **Disease or condition**
- **Trial objective**
- **Source of funding**
- **Anticipated start date**



How to Register a Trial?

In order to complete your registration and be considered for application to the registry, you must include the following information:

- **Primary outcome(s)**
- **Secondary outcome(s)**
- **Information on interventions**
- **Location of primary recruitment centre**
- **Sample size**
- **Information on collaborators**
- **Contact details**



Progress to date: Data

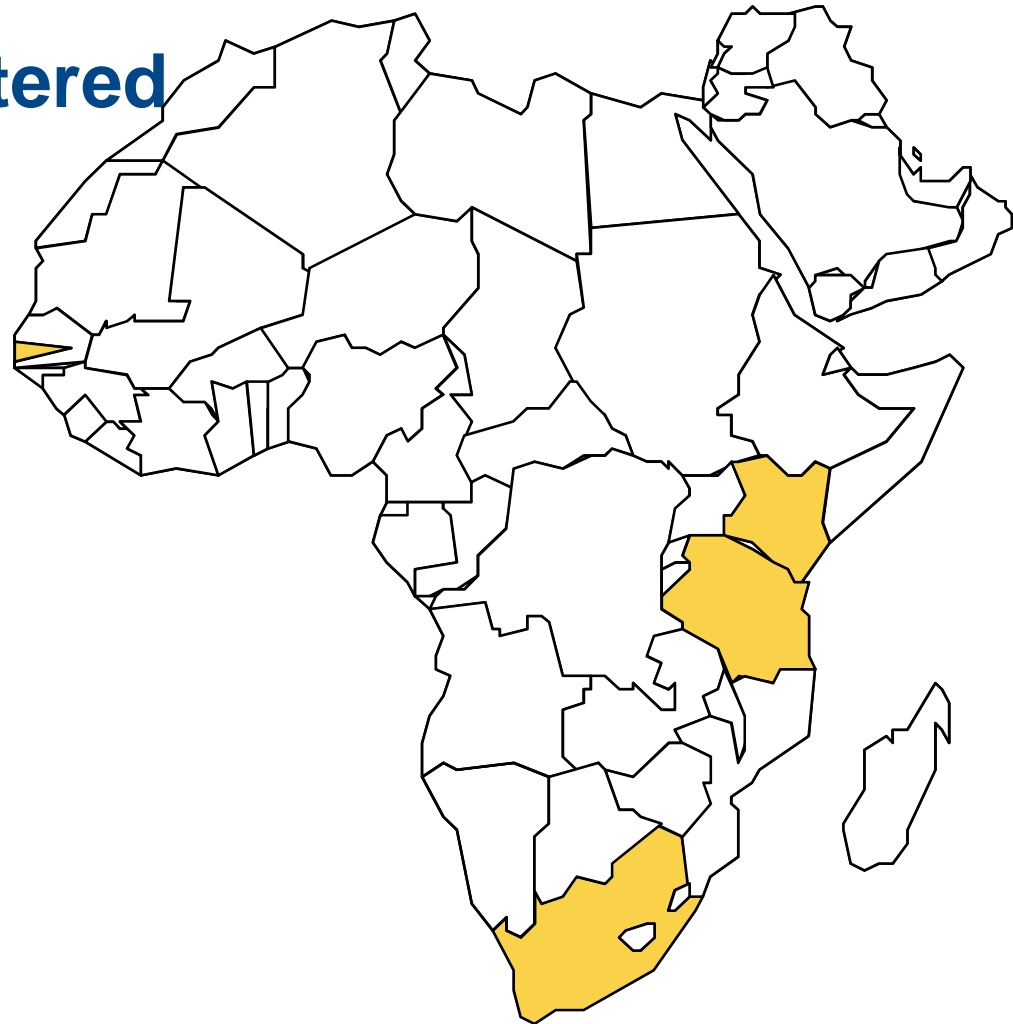
- **27 applications to the registry to date:**
 - **11 with registry numbers**
 - **5 incomplete**
 - **11 not eligible**
- **6 registered HIV/AIDS trials**
- **3 registered TB trials**
- **1 registered comorbid HIV and TB**
- **1 registered Malaria trial**



Progress to date: Data cont.

5 single-centre registered trials:

- Gambia (1)
- Kenya (1)
- South Africa (2)
- Tanzania (1)

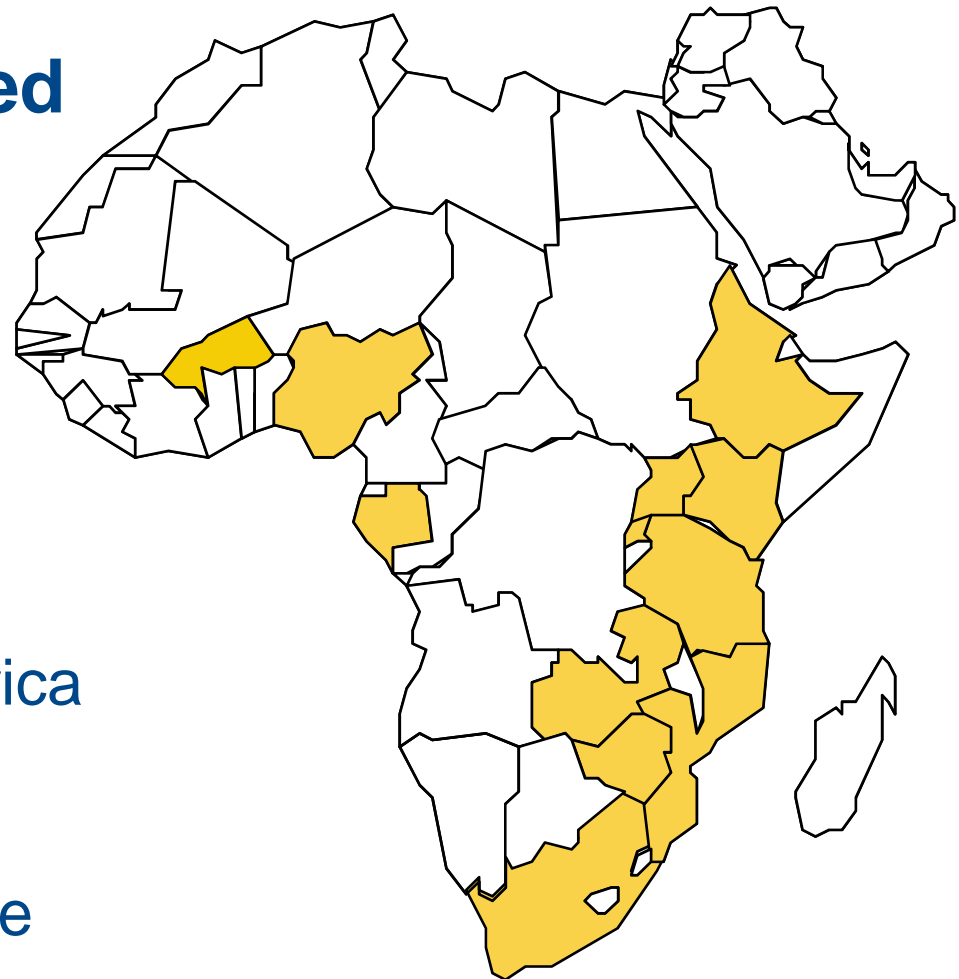




Progress to date: Data cont.

6 multi-centre registered trials in 12 African countries:

- Burkina Faso
- Gabon
- Mozambique
- Rwanda
- Tanzania
- Zambia
- Kenya
- Ethiopia
- Nigeria
- South Africa
- Uganda
- Zimbabwe





Trial Site Locations throughout Africa





Progress to date: Data cont.

- **Principal investigators:**
 - **South Africa (4)**
 - **The Netherlands (1)**
 - **United Kingdom (3)**
 - **Sweden (1)**
 - **Belgium (1)**
 - **Tanzania (1)**
- **Median sample size is 933.27 (range: 48 to 4000)**
- **Primary funders of trials are inter-government agencies, non-government organizations, governments, universities and partnerships between these**



Success in 2009

*Live portal updated and accepted as a WHO-endorsed primary registry

Publications:

- Grobler L, Siegfried N, Askie L, Hooft L, Tharyan P, Antes G. 2008. “Are national and multinational prospective trial registers necessary?” *The Lancet*, Oct 4;372(9645): pp. 1201-2.
- Abrams, A. and Siegfried, N. 2009. “Maximising the effectiveness of trial registries in resource-constrained settings (editorial).” *Clinical Evidence, BMJ*

http://clinicalevidence.bmj.com/ceweb/resources/editors-letter/full.jsp?src=editorsletter_intro



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**



Contact Information

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

Website: www.pactr.org

Email: pactradmin@mrc.ac.za

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