Pan African Clinical Trials Registry

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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
Why do research?
“... 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

#AllTrials

www.alltrials.net
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”
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
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
Advisory Group

Project manager

WHO rep.
EDCTP rep.
DoH rep.
Technical support - ANZCTR

Project Supervisor

PACTR

Project supervisor

Working Group

Project Manager
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 (CIDO), (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).*
• The database can be searched, so all trials in the region that deal with a particular condition can be reviewed providing information on the clinical trial landscape in Africa.

• The 20-item data-set provides users with information on the trial, as well as its sponsors, and collaborators.

• Research on the registry has already resulted in a number of publications, and further research on registry data is needed.

### Trial Description

<table>
<thead>
<tr>
<th>Trial no.</th>
<th>PACTR201202000354245</th>
<th>Date registered</th>
<th>2012/02/01</th>
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**Public title**

| Bridging Trial of Bivalent Killed Oral Cholera Vaccine in Ethiopia |

**Official scientific title**

| A RANDOMIZED, DOUBLE-BLIND, CONTROLLED TRIAL TO EVALUATE THE SAFETY AND IMMUNOREACTIVITY OF KILLED BIVALENT (01 AND 0139) 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)**

| |

**Dis ease(s) or condition(s) being studied**

| Cholera |

**Purpose of the trial**

| Prevention |

**Anticipated trial start date**

| 2012-03-12 |

**Actual trial start date**

| 2012-03-12 |

**Anticipated date of last follow up**

| 2012-09-10 |

**Actual date of last follow up**

| |

**Anticipated target sample size (number of participants)**

| 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.
<table>
<thead>
<tr>
<th>Sponsor level</th>
<th>Name</th>
<th>Street address</th>
<th>City</th>
<th>Postal code</th>
<th>Country</th>
<th>Nature of sponsor</th>
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<tr>
<td>Primary Sponsor</td>
<td>National Liver Institute, Menoufiya University</td>
<td>Yassin Abdelghafar</td>
<td>Shebeen El-Kom, Menoufiya</td>
<td>32511</td>
<td>Egypt</td>
<td>Hospital</td>
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<tr>
<td>Ayman Alsebaey Alghoraieb</td>
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<td>Shebben El-Kom,</td>
<td>32511</td>
<td>Egypt</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Public Enquiries WHO</td>
<td>Dr Ayman Alsebaey Alghoraieb</td>
<td><a href="mailto:aymanalsebaey@yahoo.com">aymanalsebaey@yahoo.com</a></td>
<td>+201003751248</td>
<td>+29482234586</td>
<td></td>
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</tr>
</tbody>
</table>

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

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<td>Principal Investigator WHO</td>
<td>Dr Ayman Alsebaey</td>
<td><a href="mailto:aymanalsebaey@yahoo.com">aymanalsebaey@yahoo.com</a></td>
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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
The mapping component is fully searchable, user-friendly, and provides links back to the trial information. The search function can filter a variety of fields, and highlights the types of interventions for each trial location. This is the first registry to provide a GIS mapping component, allowing for a comprehensive view of clinical trial locations and information.
What is in www.pactr.org?
<table>
<thead>
<tr>
<th>Disease Type</th>
<th>Total</th>
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<tbody>
<tr>
<td>HIV/AIDS</td>
<td>43</td>
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<tr>
<td>Malaria</td>
<td>38</td>
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<tr>
<td>TB</td>
<td>22</td>
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<tr>
<td>Co-morbid (more than one condition)</td>
<td>28</td>
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<tr>
<td>Other – Non communicable</td>
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<tr>
<td>Other - Communicable</td>
<td>11</td>
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<tr>
<td>Maternal and child health</td>
<td>63</td>
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<tr>
<td>All Diseases</td>
<td>1</td>
</tr>
<tr>
<td>Trial conduct</td>
<td>1</td>
</tr>
</tbody>
</table>
Trial sites

- Gambia (12)
- Burkina Faso (10)
- Nigeria (32)
- Gabon (7)
- Zambia (12)
- South Africa (124)
- Mozambique (11)
- Zimbabwe (10)
- Tanzania (26)
- Uganda (35)
- Rwanda (3)
- Kenya (35)
- Congo (Kinshasa) (5)
- Benin (4)
- Cameroon (6)
- Ghana (13)
- Guinea (2)
- Guinea-Bissau (5)
- Mali (5)
- Senegal (5)
- Sudan (5)
- DRC (4)
- Libya (2)
- Egypt (64)
- Ethiopia (7)
- Lesotho (2)

1 – 2 sites
3 – 4 sites
5 – 6 sites
7 – 8 sites
9 – 11 sites
12 - 25 sites
26 – 125 sites
African principle investigators

- The Gambia (7)
- Burkina Faso (4)
- Nigeria (21)
- Gabon (1)
- South Africa (57)
- Egypt (60)
- Sudan (4)
- Ethiopia (2)
- Uganda (25)
- Kenya (26)
- Tanzania (8)
- Mozambique (2)
- Zambia (2)
- Zimbabwe (5)
- Lesotho (2)
- Malawi (8)

**Key:***
- 1 - 2 investigators
- 3 - 4 investigators
- 5 - 8 investigators
- 9 - 15 investigators
- 16-30 investigators
- 31 – 60 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

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](http://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](http://www.pactr.org)
Email: pactradmin@mrc.ac.za or epienaar@mrc.ac.za
Telephone: +27 21 938 0835
Fax: +27 21 938 0836
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