WHO Global Clinical Trials Register

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2 April 2004

WHO announced registration and assignment of a unique ID (ISRCTN) for all their trials
What are the problems?

– Wasteful duplication of research
– Lost opportunities for collaboration
– Wasteful and biased under-reporting of research
  • Only about 50% of all trials are published
– Biased over-reporting of research
– Ambiguity about independence of trials/sites
– Inefficient and slow enrollment in clinical trials
– Unethical exploitation of trial participants when trial results are not made public
  • Especially if profits are made but data are kept secret
20 million men
600,000 prescribing physicians
130 clinical trials

It's amazing how much a pill can accomplish in 5 years.

After 5 years, our proven efficacy and safety profile speaks for itself. The same holds true for our experience. VIAGRA is proven for erectile dysfunction (ED) in men with a broad range of comorbid conditions—hypertension, hyperlipidemia, diabetes, depression, BPH, and men who have undergone prostate surgery.

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To learn more, call 1-888-4VIAGRA. Or visit www.viagraMD.com.
What is the size of the problem?

As many as 60,000 trials are estimated to be ongoing each year in US alone.
What is the solution?

Registers of clinical trials

– Ongoing trials, registered prospectively
  • Many registers, few are systematically constructed
    little or no coordination

– Published trials
  • Cochrane CENTRAL Register of Controlled Trials
    (>400,000)
Where are we now?

Proliferation of registers, yet no “comprehensive” register

– In US alone we have counted >300 registers online as of April 2004
Current Trials Registration Activities

- **Worldwide** – WHO registers its trials and obtains ISRCTNs

- **Europe** - European Science Foundation recommends registration with Current Controlled Trials’ *meta*Register

- **UK** – All publicly funded trials registered in *meta*Register with ISRCTNs

- **Spain** - Registration of clinical trials, and publication of drug company trials, legally mandated

- **US** - legislation mandates registration of trials for serious and life threatening diseases (www.ClinicalTrials.gov), but <50% of industry cancer trials listed
TrialsCentral provides free and confidential access to listings of clinical trials. This information about current clinical research studies helps to support informed, evidence-based decision making in healthcare.

The Clinical Trials page has an easy-to-use database of clinical trials registers. Search by health condition, such as cancer or diabetes, and by geographic location of the trials.

The Frequently Asked Questions (FAQ) page can help you learn more about clinical trials. You may want to read this before beginning your search for trials.

The Resources page has links to further health care information sites, including medical dictionaries, published [or recent] articles, and links to other evidence-based health care sites.

Contact us with comments, questions, or to report problems with the site.

Please complete the Questionnaire if you maintain a database of clinical trials. Join us at TrialsCentral in our efforts to make clinical trials information more accessible to everyone.

This site is dedicated to Diana Anderson.
ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. Before searching, you may want to learn more about clinical trials.

**arch Clinical Trials**

Example: heart attack, Los Angeles

**arch by Specific Information**

Focused Search - search by disease, location, treatment, sponsor...

**browse**

Browse by Condition - studies listed by disease or condition
Browse by Sponsor - studies listed by funding organization

**source Information**

Understanding Clinical Trials - information explaining and describing clinical trials
What's New - studies in the news
MedlinePlus - authoritative consumer health information
Genetics Home Reference - consumer information about genes and genetic conditions
NIH Health Information - research supported by the National Institutes of Health
Clinical Trials

Cardialysis is involved in many clinical trials. Some of these are listed below with the approval of the relevant sponsor. The trials that are currently in the recruiting, follow-up or reporting phase are listed under "ongoing". Trials in the final phase of reporting are listed under "completed".

Click on the trial name to get a detailed protocol outline. The protocol outline has further links to presentations at major congresses of cardiology and publications.

### Ongoing Clinical Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Sponsor</th>
<th>Status</th>
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<tbody>
<tr>
<td>ACS 99-329</td>
<td>Advance</td>
<td>Benestent I - 5 year Follow-Up</td>
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<tr>
<td>Bridge</td>
<td>Convertible</td>
<td>Danami-2</td>
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<td>Director</td>
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For Use By Healthcare Researchers and Professionals Only

About The GlaxoSmithKline Clinical Trials Register

Version 1.0 Release Date 27/9/1999

GlaxoSmithKline has a global quest to improve the quality of human life by enabling people to do more, feel better and live longer. Welcome to the GlaxoSmithKline Clinical Trials Register.

This register has been developed to provide healthcare professionals and researchers with information on the company's clinical trials programmes. GlaxoSmithKline recognises the growing importance of evidence-based medicine and the needs of our customers. Decision makers, including healthcare purchasers and providers, require access to clinical trials information, thereby facilitating awareness of the full range of current research undertaken in a specific area.

Openness and access to information on clinical trials can improve patient care, which is why GlaxoSmithKline has taken the lead in developing a policy to register clinical trials so that they are accessible to healthcare professionals and researchers outside the company.

The Clinical Trials Register provides a comprehensive record of all phase II-IV studies conducted on GlaxoSmithKline's newly registered medicines.
Why should clinical trials be registered?

There are a number of reasons why it is important to register clinical trials. It has been well documented that trials that have positive or exciting results are more likely to be published in medical journals than those with negative or inconclusive results. This means that the medical literature might represent a biased point of view on any given treatment in a particular disease. Clinical trials are registered at or near the time that they are set up and so before the results of the trial are known. Because of this, the information on trial registers is not affected by the same biases as the medical literature. In this way, even trials that are never published can contribute to the body of evidence that doctors and researchers call upon to help them to make decisions about treatments.

As well as this very important reason, trial registers provide a public record of all trials that are being done in a particular disease, or a particular region and so make it very easy for anyone who is interested to find out about what trials are being done. This means that whatever the reason, people can find information that is useful to them. For example a patient interested in what trials are being done that they could take part in; a doctor looking for a trial to enter one of his or her patients in to; a researcher finding trials that might help them to get a clear picture of how well a treatment works or someone from a charity thinking about whether or not to fund a new trial.
What is needed

A virtual unified register
- Standardization across registers
- Minimal dataset
- Centralized processing and dissemination
Welcome to Current Controlled Trials

Current Controlled Trials features two innovative clinical trial resources

**ISRCTN**

ISRCTN Register
Database of randomised controlled trials with an International Standard Randomised Controlled Trial Number (ISRCTN)

[click here to enter]

213 sponsors 1874 records

**mRCT**

metaRegister of Controlled Trials (mRCT)
International database combining registers of ongoing randomised controlled trials in all areas of healthcare

[click here to enter]

27 registers 16,113 records

Current Controlled Trials is published by BioMed Central, an independent publishing house committed to providing immediate free access to peer reviewed biomedical science.
Recommended steps for WHO

- Develop register of all controlled trials supported by WHO, using unique IDs (ISRCTNs)
- Prepare an article outlining WHO’s plans for a trials register
  - Appoint Trial Registration Advisory Group, with broad representation
  - Organize WHO’s virtual register
A reminder of the problems

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