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News

Clinical Trials in Children site launched
The WHO International Clinical Trials Registry Platform (ICTRP) launched the Clinical Trials in Children website on 19th January 2009. The aim of the site is to improve awareness and make it easier to access accurate, up to date, understandable information relevant to the conduct of clinical trials in children.

This site has been developed in association with WHO's make medicines child size initiative, the aim of which is to promote the development of, and access to, appropriate and quality medicines for children. This initiative was given a boost on 21st January 2009 with the announcement of a US$ 9.7 million grant from the Bill & Melinda Gates Foundation for WHO and UNICEF to conduct crucial research in children’s medicines with the aim of increasing the number of child-size medicines designed and formulated specifically for children.

ICTRP has also added a clinical trials in children filter to its trials search portal. This allows users to restrict their searches to clinical trials conducted in children by simply ticking a box in the portal’s Advanced Search page.

More information about how and why the filter was developed is available on the Clinical Trials in Children website.

ICTRP welcomes your comments and feedback on the Clinical Trials in Children website and search filter.

Journal of Evidence-Based Medicine theme issue on clinical trials registration
The latest issue of the Journal of Evidence-Based Medicine, due to be published online by mid March 2009, will focus on the progress made in clinical trials registration over recent years and includes articles from five WHO Primary Registries.

In their covering commentary, Davina Gherisi and Tikki Pang review the key events in trial registration since 2004 and outline the remaining challenges in establishing registration of all trials worldwide.

Other articles in the theme issue include:
Hanna Hasselblatt and colleagues outline the advantages of implementing the German Clinical Trials Register as a bilingual registry and discuss the registry's strategy of working with ethics committees and partner registries to capture trial registration data.

In two separate papers, Youping Li and colleagues assess the quality of trial registration data in different registries and propose trial registration as part of a strategy to promote the development of evidence-based medicine in China.

Udaya Ranawaka and colleagues show how establishing the Sri Lanka Clinical Trials Registry has had a galvanising effect on clinical research in Sri Lanka.

Tomonori Shiokawa shows how three major clinical trials registries have come together to form the Japan Primary Registries Network.

Masoud Solaymani-Dodaran and colleagues set out the need for an Iranian Registry of Clinical Trials, how it was implemented and the main challenges they believe need to be addressed when establishing a new registry.

Plans for regional trials registries in Africa and Latin America

The ATM Clinical Trials Registry, based in South Africa, has until now been a disease-specific, regional register of HIV/AIDS, Tuberculosis and Malaria trials conducted in Africa. The ATM Registry is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP). In January 2009 the EDCTP announced that the scope of the registry will be extended to include all clinical trials that are conducted in Africa. »Read the EDCTP's announcement.

Meanwhile, BIREME has published an article in its January newsletter (also available in Spanish and Portuguese) discussing its plans to develop a common platform for clinical trials registration in Latin America and the Caribbean. BIREME is working with the Pan American Health Organization's Research Promotion and Development team and the ICTRP to ensure that the common platform conforms to WHO trial registration standards.

Workshop on registering clinical trials in the Eastern Mediterranean countries

The Ministry of Health in Bahrain will be hosting a regional workshop in June 2009, organized by WHO's Eastern Mediterranean Regional Office (EMRO) in collaboration with the ICTRP. The workshop aims to highlight the importance of clinical trials, the need to register clinical trials in a publicly accessible registry and the role registries can play in improving the ethical and scientific quality of research conducted in the EMRO countries.

European Clinical Trials Database publishes list of data to be made publicly available

The European Commission has published the list of fields contained in the European Clinical Trials Database (EudraCT) that are to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004 and its implementing guideline 2008/C168/021. The data to be released includes information about trial protocols and about trial results. Recording trial details in EudraCT is mandatory for any clinical trial on medicinal products for human use if at least one site is in the European Union, but this information has not yet been made publicly available.

Public meeting about the US Food and Drug Administration Amendments Act 2007

Section 801 of the U.S. Public Law 110-85 (The Food and Drug Administration Amendments Act of 2007) expanded the information to be registered with ClinicalTrials.gov, including the registration of results of clinical trials.

A public meeting is being held under the provisions of this law at Lister Hill National Center for Biomedical Communications, Bethesda, MD on 20 April 2009 for interested parties to give their opinions on the new regulations for the expanded registry and results data bank.
Frequently asked questions

Question:
How should a record on a clinical trials register be cited?

Answer:
Based on the guidelines for Vancouver style referencing for Part of a database on the internet, and the Citing Medicine guidelines of the National Library of Medicine (NLM) it is recommended that a citation of a record on a trial register consist of:
- the name of the database
- the location and name of the publisher of the database
- the year the site was first developed/online
- the unique ID - the title of the record
- the date of registration
- the date when it was cited
- the approximate number of pages
- the web address of the record

For example:


More examples are provided in this PDF file.

Recent publications of interest

(See also the news article above about the Journal of Evidence-Based Medicine's theme issue on trial registration)

Listing of the publications below does not imply WHO endorsement.

Duley L, Tharyan P. Ensuring health care decisions are informed by all of the evidence: the role of trial registration. Cad Saude Publica. 2008 Dec;24(12):2732.
http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0102-311X2008001200001&lng=en&nrm=iso&tlng=en [English] [Also available in Portuguese]


http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.1000034

http://jrsm.rsmjournals.com/cgi/content/full/102/1/4
http://content.nejm.org/cgi/content/full/360/8/824

Publicity material
Help us to raise awareness of trial registration and of the WHO International Clinical Trials Registry Platform (ICTRP). Please contact us if you are organizing a meeting and would like to distribute postcards or other material about the ICTRP to delegates.

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The WHO Registry Platform e-Note is scheduled for publication on the last Friday of every second month. The next e-Note is scheduled for circulation on Friday 24th April 2009. Suggestions for the next edition can be sent to via http://www.who.int/trialsearch/Contact.aspx.

Subscription via LISTSERV: Please send an e-mail to listserv@who.int with "subscribe ictrpnews first_name last_name" in the body of the message (without any " "). The subject line can be left blank.