News

Two more data providers added to the ICTRP search portal
The Sri Lanka Clinical Trials Registry and the Iranian Registry of Clinical Trials recently became International Clinical Trials Registry Platform (ICTRP) data providers. Trial registration records from these two registries can now be searched and viewed via the ICTRP Search Portal.

Argentina makes trial registration a legal requirement
The Ministry of Health in Argentina passed a resolution in February 2009 to create the "Registry of Clinical Trials in Humans" to promote greater transparency of clinical research in Argentina. All clinical trials conducted in Argentina will have to be registered on this registry which will provide public access to the WHO Trial Registration Data Set. The law stipulates penalties for trial sponsors failing to register their trials.

The creation and administration of the registry will be the responsibility of the Secretariat of Policy, Regulation and Institutes at the Ministry of Health, and is expected to be operational by late 2009. » Read the resolution in full [Spanish only].

European Medical Research Councils call for trial registration
The European Medical Research Councils, which is part of the European Science Foundation, published a "Forward Look" report on Investigator-Driven Clinical Trials in March 2009. The report contained 26 recommendations for improving clinical research in Europe. Recommendation 14 on the publication of clinical trials results was that:

- Negative results as well as positive results are published;
- Sponsors, funders and all responsible organizations be obliged to register and publish all clinical trial data regardless of the type of trial or the phase;
- The WHO recommendations and the WHO clinical trial platform should be implemented through national governments quickly and registration should be free of charge and done rapidly;
- The quality of data deposited in clinical trials registries be improved;
- The transfer of results into clinical practice be facilitated.

Best Practice Group agrees three more minimum standards
The International Clinical Trials Registry Platform (ICTRP) Best Practice Group has agreed three new minimum standards documents since January 2009. These set out minimum standards of best practice in the use of audit trails, the translation of the WHO Trial Registration Data Set by multi-
lingual registries and the recording secondary trial identifiers. The documents also describe options for registries to go above and beyond the minimum standards.

The group previously agreed eight minimum standards at its meeting in September 2008 and will be considering six further minimum standards documents over the next three months. All minimum standards documents are available to members of the ICTRP Registry Network via a dedicated website.

Public registration of device trials
Those familiar with the FDAAA 2007 (USA) will be aware that this law prevents data on clinical trials of devices that are not yet approved for any use by the FDA from being made public when the trial is registered on ClinicalTrials.gov (referred to as the "lock box"). Many are working to change the regulations so that registrants will be able to elect to have their trial listed publicly. The trials in the "lock box" become public once the device is approved for any use by the FDA. Registered data on trials of devices that are approved for use by the FDA must be posted publicly.

If investigators of affected trials want their trial to meet international requirements for transparency and the ICMJE requirements for publication, then they will need to ensure that their trial is included on a WHO Primary Registry – even if the trial is already registered on ClinicalTrials.gov. We would strongly recommend that trial investigators make sure that the trial registration numbers allocated by each registry are entered as secondary identifiers on other registries so that the records can be linked on the ICTRP Search Portal. The ICTRP advises that trials should only be included on more than one registry if it is absolutely necessary (see http://www.who.int/ictrp/utrn/en/).

Public meeting about the Food and Drug Administration Amendments Act 2007
A public meeting was held on 20 April 2009 as required by the FDAAA 2007 (USA). The aim was to provide interested parties with the opportunity to give their opinion on the new regulations for the expanded registry and results data bank. The presentations and public submissions made, and a videocast of the event, are now available at the meeting's web page. It is still possible to submit written comments. For details go to http://www.regulations.gov. Comments should be submitted by 22 June 2009.

Australian National Ethics Application Form facilitates trial registration
In Australia, the National Ethics Application Form (NEAF) now asks applicants to ethics committees that use the form to provide details of trial registration. From the NEAF web site:

"NEAF is a web-based tool that has been developed to enable researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees (HRECs), and to assist HRECs to consistently and efficiently assess these proposals. It has been designed to meet the requirements of relevant guidelines with the aim of increasing the efficiency and quality of the ethical review process for all parties involved."

New feature in the ICTRP Search Portal
Version 3.1 of the ICTRP Search Portal, released on 30 April 2009, provides direct links to individual trial registration records based on the main trial registration ID issued by the data provider. For example, the record with a main trial registration ID of ISRCTN91899513 can now be viewed directly via the following link: http://www.who.int/trialsearch/trial.aspx?trialid=ISRCTN91899513.

Upcoming presentations
- **Clinical Trials, Globalization and Global Health - A Search for Meaning.**
  Tikki Pang, Director of WHO's Research Policy & Co-operation Department, at the Society for Clinical Trials 30th Annual Meeting, Atlanta, USA. 4 May 2009.
Recent publications of interest

From Mexico to Mali: four years in the history of clinical trial registration
Davina Gherzi, Tikki Pang

Listing of the publications below does not imply WHO endorsement.

Assessment of registration quality of trials sponsored by China
Xuemei Liu, Youping Li, Xinting Yu, Juan Feng, Xunshu Zhong, Xiaoyan Yang, Jing Li

Prospective Registration of Clinical Trials in India: Strategies, Achievements & Challenges
Prathap Tharyan

Establishing the Sri Lanka Clinical Trials Registry
Udaya K Ranawaka, Colvin Goonaratna

Iranian Registry of Clinical Trials: path and challenges from conception to a World Health Organization primary register
Masoud Solaymani-Dodaran, Afshin Ostovar, Davood Khalili, Muhammad Vasei

The German Clinical Trials Register: challenges and chances of implementing a bilingual registry
Hanna Hasselblatt, Gabriele Dreier, Gerd Antes, Martin Schumacher

Background, introduction and activity of the Japan Primary Registries Network
Tomonori Shiokawa

A call for more transparency of registered clinical trials on endometriosis
Sun-Wei Guo, Lone Hummelshoj, David L. Olive, Serdar E. Bulun, Thomas M. D’Hooghe, Johannes L.H. Evers

Patients and the public deserve big changes in evaluation of drugs
Silvio Garattini, Iain Chalmers
BMJ 2009 Mar;338:b1025. doi:10.1136/bmj.b1025

[Brazilian Registry of Clinical Trials (Rebrac): strengthening of clinical trials management in Brazil]
Departamento de Ciência e Tecnologia, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Ministério da Saúde.

Public disclosure of clinical research
Ellen Strahlman, Frank Rockhold, Andrew Freeman
The Lancet. 2009 Apr; 373: 1319-1320. doi:10.1016/S0140-6736(09)60613-9
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.

Contact us

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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 26th June 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 ictpnnews first_name last_name” in the body of the message (without any “ “). The subject line can be left blank.

Previous issues of the eNote are available at http://www.who.int/ictrp/news/enote/en/index.html