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News

Two more registries join the family of WHO Primary Registries

The German Clinical Trials Register (<http://www.germanctr.de/>) was announced as a WHO Primary Registry at the Cochrane Colloquium in Freiburg, Germany on 3rd October 2008.

The Japan Primary Registries Network was announced as a WHO Primary Registry on 17th October 2008. Japanese readers can see the statement made by the Ministry of Health, Labour and Welfare at <http://www.mhlw.go.jp/topics/2008/10/tp1017-1.html>. The Network is made up of three registries with records in both English and Japanese:

- University Hospital Medical Information Network (UMIN)
<http://www.umin.ac.jp/ctr/>
- Japan Pharmaceutical Information Center - Clinical Trials Information (JapicCTI)
http://www.clinicaltrials.jp/user/cte_main_e.jsp
- Japan Medical Association - Center for Clinical Trials (JMACCT)
https://dbcentre3.jmacct.med.or.jp/jmacctr/Default_Eng.aspx

Registering trials with the German Clinical Trials Register and the Japan Primary Registries Network now satisfies the trial registration policies of many medical journals (http://www.who.int/ictrp/trial_reg/en/index2.html) .

Congratulations to our colleagues in Germany and Japan on their achievements.

Declaration of Helsinki calls for mandatory registration of clinical trials

The World Medical Association revised the Declaration of Helsinki on October 18th, 2008 at its General Assembly in Seoul, South Korea. The new version at <http://www.wma.net/e/policy/b3.htm> replaces all previous versions.

Of particular interest to the WHO International Clinical Trials Registry Platform are paragraphs 19 and 30:

19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and

inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Paragraph 19 is a significant change from previous versions of the Declaration. The World Medical Association is calling for mandatory registration of clinical trials.

Frequently asked questions

Question:

What is trial registration?

Answer:

The WHO regards trial registration as the publication of an internationally-agreed standard data set (<http://www.who.int/ictcp/network/trds/en/index.html>) about a clinical trial on a publicly-accessible website managed by a registry conforming to WHO standards (http://www.who.int/ictcp/network/criteria_summary/en/index.html).

Presentations & events

Working Group on Best Practice for Clinical Trial Registries



From left to right: Chris Jones (WHO), Lisa Askie (Australia New Zealand Clinical Trials Registry), Ludovic Reveiz (LatinRec), Ghassan Karam (WHO), Lakshmi Grama (Physician Data Query), Hazim Timimi (WHO), Davina Ghersi (WHO), Lotty Hooft (Netherlands National Trial Register), Taixiang Wu (Chinese Clinical Trial Register), Gabriele Dreier (German Clinical Trial Register), Masoud Solaymani-Dodaran (Iranian Registry of Clinical Trials), Ambujam Kapoor (Clinical Trials registry – India), Hideyuki Kondo (Japan Primary Registries Network), Takahiro Kiuchi (Japan Primary Registries Network)
(Photo: Taixiang Wu)

Participants from 10 registries took part in the meeting of the Working Group on Best Practice for Clinical Trial Registries in Geneva 29-30 September 2008. The meeting agreed minimum operating standards for clinical trial registries on establishing the existence of trials and registrants, ensuring trial records are valid and complete, handling retrospective registration and unique trial identification.

Presentations

The ICTRP presented talks at:

- The Pre-conference on Medicines for Children at the 13th International Conference of Drug Regulatory Authorities, Bern, Switzerland, 14-15 September 2008.
- The 16th Cochrane Colloquium, Freiburg, Germany 3-7 October 2008. Poster presentation "Accessing the Evidence: A search portal and reference site for clinical trials in children" (http://www.cochrane.org/colloquium/2008/virtual_posters/?poster=136)
- The Drug Information Agency workshop on Clinical Trial Disclosure, Chicago, USA, 15-16 October 2008
- Satellite meeting on the Integration of Ethical Review, Registration and Regulation of Clinical Trials in Africa at the Third Meeting of The African Vaccines Regulatory Forum (AVAREF), Zanzibar, Tanzania, 27-30 October 2008.

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.

Recent publications of interest

Listing of the publications below does not imply WHO endorsement.

Ramsey S, Scoggins J. Commentary: Practicing on the Tip of an Information Iceberg? Evidence of Underpublication of Registered Clinical Trials in Oncology. *The Oncologist* 2008;13:925-929.
DOI: 10.1634/theoncologist.2008-0133

<http://www.theoncologist.com/cgi/reprint/theoncologist.2008-0133v1.pdf>

Lee K, Bacchetti P, Sim I. Publication of Clinical Trials Supporting Successful New Drug Applications: A Literature Analysis. *PLoS Medicine* 2008;. Vol. 5, No. 9, e191 DOI:10.1371/journal.pmed.0050191

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050191>

Grobler L, Siegfried N, Askie L, Hooft L, Tharyan P, Antes G. National and multinational prospective trial registers. *The Lancet*. 2008; 372:1201-1202. DOI:10.1016/S0140-6736(08)61498-1

<http://www.thelancet.com/journals/lancet/article/PIIS0140673608614981/>

Normile D. The Promise and Pitfalls of Clinical Trials Overseas. *Science* 2008; 322(5899): 214-216.
DOI: 10.1126/science.322.5899.214

<http://www.sciencemag.org/cgi/content/full/322/5899/214>

Gherzi D, Pang T. En route to international clinical trial transparency. *The Lancet*. 2008; 372:1531-1532. DOI:10.1016/S0140-6736(08)61635-9

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(08\)61635-9/](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61635-9/)

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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 19th December 2008. Suggestions for the next edition should be addressed to ictrpinfo@who.int with "e-Note" in the subject line.

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.

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