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News**Brazil legislates to establish clinical trial registration**

The Brazilian health regulation authority (Agência Nacional de Vigilância Sanitária - ANVISA) recently passed a law (Resolução da Diretoria Colegiada - RDC Nº 39, de 5 de Junho de 2008, <http://e-legis.anvisa.gov.br/leisref/public/showAct.php?id=31279>) making it compulsory to register all phase III trials in a WHO Primary Registry or an ICMJE-approved registry.

The Brazilian Ministry of Health has also formed a commission to specify and implement in 2009 a Brazilian registry of clinical trials that conforms to WHO Criteria for Primary Registries. It will be known by its Portuguese acronym REBRAC and its development work is being carried out in coordination with the Pan American Health Organization's Latin American and Caribbean Center on Health Sciences Information (BIREME; <http://www.bireme.br/>) based in Brazil, which is a member of the new commission.

PAHO's Research Promotion and Development team and BIREME are jointly working to develop a common platform for clinical trials registration in Latin America and the Caribbean, and a strategy to promote adherence to WHO-compliant trial registration standards.

Revamp of the ICTRP website

The International Clinical Trials Registry Platform (ICTRP) website at has been updated and reorganized. Information on the role of data providers (<http://www.who.int/ictrp/search/en/>) and better information on Primary Registry criteria

(http://www.who.int/ictrp/network/criteria_summary/en/index.html) are among the many changes that have been made. Please visit the website at <http://www.who.int/ictrp> and send us your comments and suggestions via the 'contact us' page at <http://www.who.int/trialsearch/Contact.aspx>



Clinical Trials in Children portal to be launched in October

The International Clinical Trials Registry Platform (ICTRP) will be launching the *Clinical Trials in Children* website in October 2008 to provide easy access to information about paediatric clinical trials.



Frequently asked questions

Question:

Can I register my trial with the WHO International Clinical Trials Registry Platform (ICTRP)?

Answer:

No. WHO does not maintain its own registry so you cannot register your trial directly with us. To register your trial, submit the details directly to any one of the WHO Primary Registries (<http://www.who.int/entity/ictrp/network/primary/en/index.html>) or an ICMJE-approved registry (<http://www.icmje.org/faq.pdf>).

To meet the requirements of the International Committee of Medical Journal Editors (ICMJE) you can register your trial with any WHO Primary Registry or an ICMJE approved registry.

To meet WHO requirements for transparency and publication, it is only necessary for your trial to be registered once, in either a WHO Primary Registry or an ICMJE approved registry.

NOTE: Regulatory, legal, ethical, funding and other requirements for oversight and conduct of clinical trials differ from country to country. It is recommended that those responsible for conducting a clinical trial check to make sure they are complying with the specific requirements of each country.

Presentations & events

The Working Group on Best Practice for Clinical Trial Registries will be meeting on 29-30 September 2008 to agree minimum standards of best practice for Primary Registries (<http://www.who.int/ictrp/network/primary/en/index.html>). Administrators of nine registries will come together to work on the standards at the meeting hosted by the ICTRP secretariat at WHO headquarters in Geneva, Switzerland.

The ICTRP will be presenting 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 Cochrane Colloquium, Freiburg, Germany, 3-7 October 2008.
- The Drug Information Agency workshop on Clinical Trial Disclosure, Chicago, USA, 15-16 October 2008
- The African Vaccines Regulatory Forum (AVAREF), Dar Es Salaam, 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

Clinical trials in India: ethical concerns. *Bulletin of the World Health Organisation*. 2008; 86(8). <http://www.who.int/bulletin/volumes/86/8/08-010808/en/index.html>

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 31st October 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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