



International Clinical Trials Registry Platform Newsletter

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1. From the Registry Platform

Over the past three months, the Registry Platform has made substantial progress:

Meetings held:

- Scientific Advisory Group, 1st meeting (17-18 November 2005)
- International Advisory Board, 1st meeting (6 February 2006)

Definition of norms and standards:

- Scope of trial registration
- Minimum Trial Registration Data Set (Version 1.0)
- Composition and structure of the Registers Network
- Testing of data interchange standards

These achievements will be detailed further in this Newsletter.

Secretariat staffing:

Some personnel changes have also taken place within the Secretariat since the beginning of 2006:

On **1 January**, Dr Ida Sim returned to her faculty position at the University of California at San Francisco [<http://rctbank.ucsf.edu/sim/sim.html>].

She remains the Project Coordinator for the Registry Platform.

On **6 January**, Dr An-Wen Chan joined the Registry Platform as its Scientific Officer. He has been seconded from the Department of Medicine at the University of Toronto, Canada with support from the Canadian Institutes of Health Research (CIHR). His assignment lasts through June 2006.

After receiving his medical degree from the University of Calgary, Canada, Dr Chan completed a doctorate in Public Health & Clinical Epidemiology as a Rhodes Scholar in Oxford, UK. In 2004, he was appointed special advisor for the Randomized Controlled Trials Unit at the Canadian Institutes of Health Research. He also serves on the editorial board of the journal PLoS Clinical Trials.

Upcoming meetings:

A special session on disclosure timing will be held in Geneva on 26 April 2006.

The 2nd Scientific Advisory Group meeting will be held in Geneva on 27-28 April 2006.

The 1st Annual WHO Trial Registration Conference will take place at the WHO Kobe Centre in Kobe, Japan from 29 November - 1 December 2006.

2. Scientific Advisory Group and International Advisory Board

First Meeting of the Scientific Advisory Group (17-18 November 2005)

The **Scientific Advisory Group** (SAG), co-chaired by Prof Kay Dickersin and Dr Richard Horton, is composed of international experts who represent key stakeholders involved in clinical trials. The SAG advises on the principles and substantive standards for trial registration, and met for the first time in Geneva, Switzerland. Attendees agreed to key elements of global trial registration policies:

- Registration of all interventional trials is a scientific, ethical, and moral responsibility;
- At a minimum, the 20 item Data Set is required for trial registration;

- Full disclosure of all 20 items at the time of registration is critical on scientific grounds and is in the public interest.

The SAG also supported the general structure and composition of an international network of registers, and confirmed the importance of detecting multiply-registered trials.

The final meeting report is available at:
http://www.who.int/ictrp/SAG_Report.pdf

Complete list of SAG Members:
<http://www.who.int/ictrp/about/details/en/index3.html>

First Meeting of the International Advisory Board (6 February 2006)

The first meeting of the **International Advisory Board** (IAB) took place at Imperial College, London, UK. The panel of experts, consisting of 12 heads of prominent organizations in 8 countries and chaired by Sir Richard Sykes, Rector of Imperial College, endorsed the strategic plan of the Registry Platform and provided a strong vote of support.

Charged with providing broad policy and strategic guidance, the IAB supported the Registry Platform's key milestones over the next 3 years, including the launch of a network of qualified trial registers, a unique identification number for tracking trials (Universal Trial Reference Number or UTRN), and a one-stop search portal that will direct users to trial information contained in individual registers worldwide. The IAB also endorsed the Registry Platform's two-tiered approach to the proposed network of Primary and Associate Registers (see Section 5, [WHO Network of Member Registers](#)).

Sustainable funding was identified as the key requirement for ensuring success of the Registry Platform. The IAB called for additional resources to be allocated from the regular and extrabudgetary funds of the WHO, and emphasized the importance of allocating start-up funds for capacity building in developing countries.

The Secretariat would like to acknowledge and thank the Department of Health of England and the Wellcome Trust for providing financial support for this meeting.

The final minutes of the IAB meeting are available online at: http://www.who.int/ictrp/IAB_report.pdf.

The next meeting will take place in early 2007.

Photo of the Participants to the IAB Meeting, London, UK



Front row, left to right:

Sir Iain Chalmers, Ms Kathy Redmond,
Dr Ida Sim, Sir Richard Sykes, Dr Ana Langer,
Dr Ching-Li Hu

2nd row, left to right:

Dr José R. Carvalheiro, Dr Hideo Shinozaki,
Dr Tikki Pang, Dr An-Wen Chan,
Dr Nirmal Kumar Ganguly, Dr Caroline Loew,
Dr Gail H. Cassell, Dr Harold Sox

Participant missing on this picture:
Dr Pascoal Mocumbi

IAB Meeting - Full-size image:
<http://www.who.int/ictrp/news/P10I0004b.jpg>

Complete list of IAB Members:
<http://www.who.int/ictrp/about/details/en/index2.html>

3. Scope of Trial Registration

An interventional trial is defined as a research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Because ethical obligations to study participants exist regardless of study type, all

interventional trials should be registered, including early and late phase trials, trials of marketed or non-marketed products, randomized or nonrandomized trials, and trials in patients or healthy human volunteers.

4. Trial Registration Data Set (Version 1.0)

The 20 items comprising the Trial Registration Data Set (Version 1.0) have been finalized. They will remain fixed for 2 years, and will be monitored for necessary modifications at that time. Detailed explanation of each item is available at:

http://www.who.int/ictrp/data_set/en/index1.html

1. Primary Register and Trial ID number

2. Date of Registration in Primary Register
3. Secondary ID number(s)
4. Source(s) of Monetary or Material Support
5. Primary Sponsor
6. Secondary Sponsor(s)
7. Contact for Public Queries
8. Contact for Scientific Queries
9. Public Title
10. Scientific Title
11. Countries of Recruitment

12. Health Condition(s) or Problem(s) Studied
13. Intervention(s)
14. Key Inclusion and Exclusion Criteria
15. Study Type
16. Date of First Enrollment
17. Target Sample Size
18. Recruitment Status
19. Primary Outcome(s)
20. Key Secondary Outcomes

5. WHO Network of Member Registers

The WHO will establish a coordinated, international network of trial registers that will serve global health needs through a web-based platform. Acceptable registers will be approved based on criteria that are being finalized. The WHO has no plans to administer its own trial register.

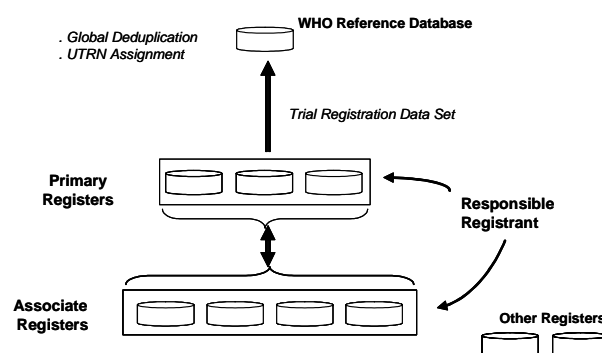
The composition of the register network has been finalized following consultation with the Scientific Advisory Group (SAG) and the International Advisory Board (IAB). It will consist of two types of registers:

- A relatively small number of national, regional, or international **Primary Registers**, which accept all trials, perform deduplication of entries within their own register, and provide data directly to the WHO;
- A larger number of **Associate Registers**, which send their registration data to designated Primary Registers. They can be either broadly-based or restricted in scope, such as a specific disease, company, or institution.

Through its six regional offices (AFRO, AMRO/PAHO, EMRO, EURO, SEARO and WPRO) and other mechanisms, the WHO is facilitating the coordination of regional approaches to trial registration worldwide.

The launch of a preliminary Network of Member Registers is planned for the 2nd quarter of 2006.

Figure: WHO Network of Member Registers



More information:

http://www.who.int/ictrp/registration/member_reg/en/index1.html

6. Registers Working Group

In March, the WHO will launch a preliminary Registers Working Group (RWG), chaired by Davina Ghersi from the Australian Clinical Trials Registry. The aims of the RWG are to discuss and

resolve organizational, technical, quality assurance, and procedural issues that are relevant to Primary and Associate Registers; to collaborate on empiric research; and to provide guidance on register-

related issues for both established and new registers.

The Working Group will advise and report directly to the Registry Platform Secretariat.

7. Presentations by the Secretariat

The Secretariat participated in the FERCAP Conference (see below) to learn more about relating ethics approval to trial registration and the roles of ethics committees within the Asia and Western Pacific Region.

Please feel free to use the following presentation, provided we receive an information note from you on how it will be used.

- **Dr Patrick Unterlerchner** - Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP) Conference. Defining the Roles, Responsibilities and Relations between National Health Authorities and Ethics Committees in Health Research, Pattaya, Thailand. 12-14 December 2005.
http://www.who.int/entity/ictrp/news/FERCAP_Dec06.pdf

Upcoming Presentations:

- **Dr An-Wen Chan** – 4th Asian-Pacific Conference on Evidence Based Medicine,

Chengdu, China. 15-17 April 2006.

<http://www.ebm.org.cn/upload/apce/apce.html>

- **Dr Ida Sim** - Clinical Trial Registries and Results Databases, Comprehensive Global Tools that Enable Transparency and Increase Patient Awareness of Clinical Trial Data, Arlington, VA, United States of America. 24-25 April 2006.
http://www.cbinet.com/show_conference.cfm?confCode=HB635
- **Mr Ghassan Karam** – CDISC 2006 European Interchange, Berlin, Germany. 24-27 April 2006
<http://www.cdisc.org/international/eu/eu.html>
- **Dr Tikki Pang** and **Dr An-Wen Chan** – Workshop and press conference on the International Clinical Trials' Day 20th May 2006, EU Commission, Brussels, Belgium. 19 May 2006.
http://www.ecrin.org/ecrin_files/news.php?level=1

8. Approximate Project Timeline

Q1 2006

- International Advisory Board Meeting
- Finalization of the WHO Registration Data Set
- Creation of Registers Working Group

Q2 2006

- Scientific Advisory Group Meeting: Advice on WHO register criteria, and other norms and standards
- Finalization of register membership criteria
- Finalization of standards for disclosure timing of registration data
- Launch of Register Network

Q3 2006

- First version of assignment of UTRNs to Member Registers
- Launch of Registry Platform Search Portal prototype

Q4 2006

- 1st Annual Registry Platform Meeting: Scientific Advisory Group, Member Registers (Kobe, Japan)
- Expansion of Register Network
- Initiation of training workshops and in-field technical assistance

9. Contact Us

We welcome your questions, comments and suggestions on any of the topics developed in this Newsletter and on the Registry Platform in general. Please send your mail to: ICTRPinfo@who.int

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