



International Clinical Trials Registry Platform Newsletter

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1. From the Registry Platform

Tribute to Dr LEE Jong-wook

It is with a great shock that WHO and the Secretariat of the Registry Platform received the news of the untimely death of Dr LEE Jong-wook, Director General, on Monday, 22 May 2006. Dr Lee believed in WHO's leadership towards the establishment of the International Clinical Trials Registry Platform and was confident it would serve both science and patients.

In May 2005, he addressed the 58th World Health Assembly in the following terms: "*We are ready to move forward with an international Clinical Trials Registry. This will do much to strengthen the research process and its ability to win public trust*".

The Secretariat will continue its efforts to move the Registry Platform forward, as Dr. Lee envisaged.



Dr LEE Jong-wook, 1945-2006, WHO Director-General

More information on Dr Lee's passing:
<http://www.who.int/dg/lee/tributes/en/index.html>

Registry Platform Activities

Several productive meetings took place over the past three months, culminating in a major policy announcement. In April, the Registry Platform held a Formal Consultation on Disclosure Timing with a broad spectrum of stakeholders in clinical trials. Based on the informative views expressed during this meeting as well as extensive preceding consultations, the Secretariat developed a policy on Disclosure Timing, which was announced on 19 May 2006 during International Clinical Trials' Day events in Brussels, Belgium. The 2nd meeting of the Scientific Advisory Group was also held in April to discuss issues surrounding the implementation of trial registration, establishment of the WHO Registers Network, and general principles of results disclosure.

Meetings held

- Formal Consultation on Disclosure Timing (26 April 2006)
- Scientific Advisory Group, 2nd meeting (27-28 April 2006)
- International Clinical Trials Day Workshop, Brussels, Belgium (19 May 2006)

Secretariat staffing

- **Dr An-Wen Chan**, Scientific Officer in the Registry Platform Secretariat, returned to the Department of Medicine at the University of Toronto, Canada at the end of June 2006.

However, he remains involved in the work of the Secretariat on a part-time basis, particularly in the development of oversight and compliance mechanisms.

- **New Coordinator** – The Secretariat received over 86 applications for the position of Registry Platform Coordinator. The selection process has now started and the new Project Coordinator is expected to take office on 1 September 2006. In the meantime, Dr Ida Sim will remain as Project Coordinator.

Upcoming meetings

- 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

Second Meeting of the Scientific Advisory Group (27-28 April 2006)

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 this April for the second time in Geneva, Switzerland. Attendees debated complex issues and provided the Secretariat with their advice on the following topics:

- **Disclosure Timing** – How to deal with trial entries that contain incomplete information? Would the availability of a delay mechanism truly improve compliance?
- **Implementation of Trial Registration Data Set, Version 1.0** – The Data Set is now finalized and will be reviewed in September 2008. The SAG discussed coding of age, gender, and “condition” for early phase studies, and discussed the pros and cons of requiring all or “key” secondary outcomes.

We would like to acknowledge CDISC (www.cdisc.org), which is helping establish a standard data interchange format for the Trial Registration Data Set.

- **Results Disclosure** – Journal publications should generally not take precedence over posting of data in results databases. The Platform should consult more broadly with journals on this topic, including journals with fewer resources.

The Scientific Advisory Group agreed that trial

registers and results databases serve separate and distinct roles.

- **Draft criteria for Primary and Associate Registers** – Both Primary and Associate Registers criteria have been revised to better frame the requirements for trial registration at different levels and in different settings.
- **Quality assurance** – The use of several UTRN (Universal Trial Reference Number) variants as part of the deduplication process was debated. Possible criteria for granting a UTRN include the uniqueness of the trial registration entry, completeness of all data entries, quality of data entries, and timing of the registered information.

Complete list of SAG Members:

<http://www.who.int/ictrp/about/details/en/index3.html>

SAG Participants, 27-28 April 2006



Missing on this picture:

Ms Anne Greenwood, Dr Jeff Drazen, Dr David Moher, Dr Jimmy Volmink and Dr Deborah Zarin.

Full-size image (with legend):

http://www.who.int/ictrp/Photo_SAG_Apr06.pdf

3. Formal Consultation on Disclosure Timing

The WHO Registry Platform Secretariat welcomed a total of 68 participants to a Formal Consultation on Disclosure Timing on 26 April 2006, in Geneva, Switzerland. The Consultation was moderated by Dr Norman Swan, broadcaster and journalist at the

Australian Broadcasting Corporation in Sydney, Australia. A large spectrum of stakeholders¹ took

¹ Ethics committees; Government; Industry (pharmaceutical, biotechnological, devices); Law; Medical journal editors; Non-governmental organizations; Patient organizations; Trial registers; Trialists/Researchers

part in the consultation, whose primary goal was to inform the Registry Platform Secretariat regarding issues pertaining to disclosure timing of registered clinical trial information. In particular, the following topics were debated:

- The benefits and problems of immediate public disclosure of intervention names and novel outcomes for registered trials;
- The benefits and problems with registering early phase uncontrolled trials;
- The feasibility of implementing a reliable delay mechanism;
- The importance of compliance mechanisms.

The considerations expressed during the Formal Consultation – and in all other previous consultative processes – helped the Secretariat make a decision on the most suitable policy for the registration of clinical trials. It was decided that:

1. all interventional clinical trials should be registered, including early phase uncontrolled trials in patients or healthy volunteers;
2. all registration data items should be publicly disclosed at the time of registration and before recruitment of the first participant. WHO does not support any mechanism for delayed disclosure.

The monitoring of compliance with the registration policy is expected to begin after 1 January, 2007.

This policy, announced in Brussels, Belgium on 19 May 2006, received broad press coverage by major news outlets (e.g., Financial Times, BBC) and magazines (e.g., The Economist) around the world, as well as by editorials and articles in major science journals (e.g., Nature, Lancet, BMJ).

Related publications

- Sim I, Chan AW, Gülmezoglu AM, Evans T, Pang T. Clinical trial registration: transparency is the watchword. *The Lancet* 2006, 367:1631-33.
- WHO Registry Platform Secretariat. Formal Consultation on Disclosure Timing - Summary. Geneva, Switzerland, 26 April 2006. http://www.who.int/ictrp/WHO_Formal_Consultation_Disclosure_Timing.pdf
- World Health Organization, News Release. The World Health Organization Announces New Standards for Registration of All Human Medical Research. 19 May 2006. <http://www.who.int/mediacentre/news/releases/2006/pr25/en/index.html>

More information on the Formal Consultation:
<http://www.who.int/ictrp/consultation/en/index.html>

4. WHO Registers Network and Registers Criteria

The WHO Registers Network is being developed in consultation with major existing registers. It is agreed that the number of Primary Registers must remain small – mainly for technical and operational reasons.

Through its work, the WHO Registers Working Group pointed out several issues needing further discussion:

- How to cover the globe with a few central “aggregator” registers, using various ‘front ends’ and ‘back ends’?
- How to coordinate issues related to the trials deduplication work, and what are the possible mechanisms for such an implementation at the regional and/or local levels?
- What mechanisms to implement in order to

ensure a good quality registration of data entries based on the revised registers criteria?

- What about the updating of data for sound Search Portal development?
- What is the possible role of WHO in validating registrants and data entries, particularly those in non-English languages?

Next steps

The Registry Platform Secretariat is planning a series of meetings and discussions to examine and clarify the issues mentioned above. The Secretariat aims for a full exchange of views with all partners on technical and administrative aspects related to the Registers Network as we move ahead on this important initiative.

5. Presentations by the Secretariat

Over the last quarter, the Secretariat staff continued its efforts to promote and explain the Registry Platform initiative around the world. It also took advantage of those international meetings to learn more about a variety of topics linked to its activities.

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

- **Dr Ida Sim** – WHO International Trial Registry Platform (audio seminar). Webcast, 45 minutes presentation and 15 minutes Q&A. 16 March 2006.
http://www.who.int/ictcp/news/ictcp_webcast.pdf
- **Dr An-Wen Chan** – 4th Asian-Pacific Conference on Evidence Based Medicine, Chengdu, China. 15-17 April 2006.
http://www.who.int/ictcp/news/Chengdu_Chan.pdf
- **Dr Ida Sim** – Clinical Trial Registries and Results Databases, Comprehensive Global Tools that Enable Transparency and Increase Patient Awareness of Clinical Trial Data, Washington DC, United States of America. 22-24 April 2006.
- **Mr Ghassan Karam** – CDISC 2006 European Interchange, Berlin, Germany. 26 April 2006.

6. 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 standards for disclosure timing of registration data

7. 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

This Newsletter is issued on a quarterly basis.

http://www.who.int/ictcp/news/WHO_IntlClinTrialsReg-Karam.pdf

- **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.who.int/ictcp/news/Brussels19May06.pdf>

More information (Workshop Report, ECRIN Web site - accessed 30 June 2006):

http://www.ecrin.org/ecrin_files/dokumente/Workshop_Report_International_Clinical_Trials_Day_2006.pdf

Upcoming Presentations

- Chan AW, Sim I, Gülmezoğlu AM, Unterlerchner P, Karam G, Evans T, Pang T. The WHO International Clinical Trials Registry Platform: Promoting science and ethics through increased transparency. MedNET 2006, Toronto, Canada [abstract accepted].
- Chan AW, Sim I, Gülmezoğlu AM, Unterlerchner P, Karam G, Evans T, Pang T. The WHO International Clinical Trials Registry Platform: Promoting science and ethics through increased transparency. XIV Cochrane Colloquium, October 2006, Dublin, Ireland. [submitted]

Q3 2006

- Transition to new Project Coordinator
- Finalization of register membership criteria
- Testing of data interchange standard

Q4 2006

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

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