



## International Clinical Trials Registry Platform Newsletter

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### 1. *From the Registry Platform*

Thank you very much for reading the first issue of the WHO Registry Platform's Newsletter.

Following the Technical Consultation on Trial Registration Standards that took place at the World Health Organization's Headquarters in Geneva, Switzerland on 25-27 April 2005, much has been accomplished towards the building of the International Clinical Trials Registry Platform.

A Secretariat has been established at WHO Headquarters in Geneva to manage the project, which involves the Research Policy & Cooperation Department (RPC) in the Evidence & Information for Policy cluster (EIP). The project Coordinator is Dr Ida Sim reporting to Dr Tikki Pang (Director, RPC) and Dr Tim Evans (Assistant Director General, EIP), assisted in her tasks by Dr Patrick Unterlechner (Technical Officer) and Mr Ghassan Karam (IT Officer).

### 2. *SAG and IAB*

The Registry Platform Secretariat is supported by two Boards, namely the "**International Advisory Board**" (IAB) and the "**Scientific Advisory Group**" (SAG).

The **IAB** is composed of 16 members. Sir Richard Sykes from the Imperial College, London, UK is the Chairman. The IAB mandate is to address issues related to strategies, policies and advocacy for clinical trials registration. The IAB meets once a year and its first meeting is scheduled on 6 February 2006 in London, UK. For more information, please visit:  
[www.who.int/ictrp/about/details/en/index2.html](http://www.who.int/ictrp/about/details/en/index2.html)

The first issue of this Newsletter focuses on the latest developments of the project as it refers to the work of the Secretariat and past accomplishments, the position of different stakeholders and where the project is heading to.

It is important to note that the WHO does not plan to create its own register. Rather, the WHO is setting rules and standards for how new and existing registers should operate, and how they should work together. Therefore, research scientists and groups should continue registering with existing registers.

Finally, the driving principle behind the WHO Registry Platform is to help uphold scientific and ethical integrity to restore public trust and confidence in medical research. We aim to accomplish our goals with broad consultation and with policies that take into account the needs and available resources of all parties.

The **SAG** is composed of 19 members. The co-Chairs are Dr. Kay Dickersin from Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA and Dr. Richard Horton, The Lancet, London, UK. The SAG objectives are to advise on standards and norms related to clinical trials registration. The SAG meets twice a year and its next meeting is scheduled on 17-18 November 2005. For more information, please visit:

[www.who.int/ictrp/about/details/en/index3.html](http://www.who.int/ictrp/about/details/en/index3.html)

### 3. Position of Key Stakeholders

The International Committee of Medical Journal Editors (ICMJE) and British Medical Journal have called for public registration of clinical trials; the ICMJE stated that, beginning 1 July 2005, only registered trials will be eligible for journal publication. For more information, please visit: [www.icmje.org](http://www.icmje.org); [www.bmj.com](http://www.bmj.com).

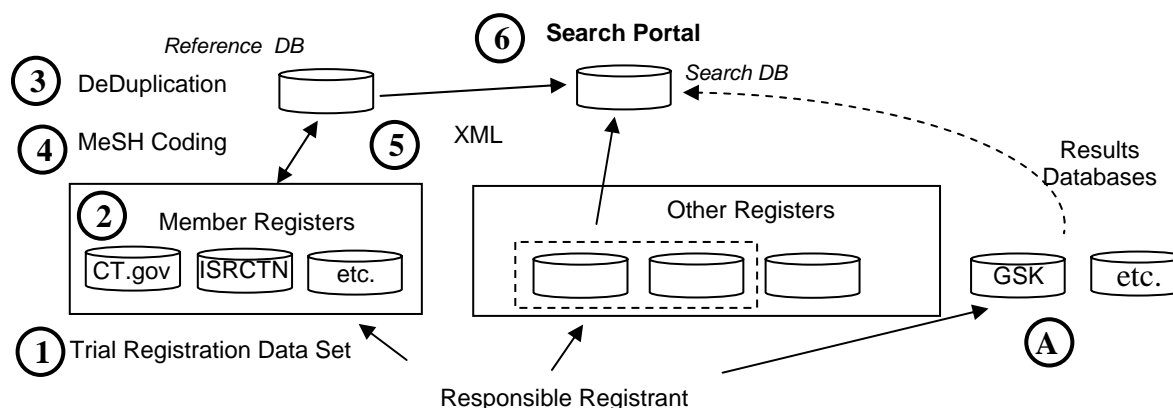
The IFPMA has launched a search portal on September 2005 in order to enable information on industry-sponsored clinical trials (other than exploratory) to be readily retrieved among a number of registries and databases. The pharmaceutical industry supports the WHO Minimum Data Set. However and due to

competitive reasons, 5 items of the Minimum Data Set are considered as sensitive and are still subject to negotiations regarding the implementation of a possible escrow mechanism. The modalities of the escrow mechanism are yet to be discussed and agreed upon. For more information, please visit: [www.ifpma.org](http://www.ifpma.org).

The US PhRMA clearly mentioned that it is willing to cooperate with WHO on the building of the International Clinical Trials Registry Platform and that all efforts will be made to reach a consensus on sensitive issues. The issue of the escrow mechanism also applies here. For more information, please visit: [www.phrma.org](http://www.phrma.org).

### 4. Where Are We Heading To?

This diagram gives an overview of how the different elements of the project interact and fit together:



The numbered items are the major deliverables of the Registry Platform project within the next year ([www.who.int/ictrp](http://www.who.int/ictrp)). The lettered items are deliverables once the numbered items are launched.

- 1. Trial Registration Data Set** (the “20 items”) – required information for registration of interventional clinical trials. Individual registers may require more than this minimum set of information. Several proposals for handling the “5 sensitive items” are being considered. (Those 5 items are regarded as sensitive for competitive reasons by some sponsor who may wish to delay the release of the information).
- 2. Network of Member Registers** – Registers that meet content, deduplication, accountability, and technical standards can become members of the Registry Platform. It

is hoped that the ICMJE will endorse the register membership criteria such that Member Registers will automatically be acceptable to the ICMJE.

The “Responsible Registrant” of a trial is responsible for ensuring that the trial is registered in one and preferably only one Member Register, and in as few additional registers as possible and only as necessary to meet local regulations.

- 3. Trial Deduplication** – It is likely that the world will continue to have multiple trial registers serving multiple, sometimes overlapping, constituencies. It is also possible that patchworks of regulations may require one trial to be registered in multiple registers. It is vital for the scientific integrity of the Registry Platform that duplicate entries within registers

are prevented, and that duplicate entries across registers are clearly identified as such.

As much as possible, deduplication should happen at the Member Register level. Currently, no entity performs trial deduplication across registers. The WHO proposes to coordinate a centralized service for deduplicating trials across registers. Deduplication will be performed by a consortium of deduplication providers who have previous experience in performing this difficult task. This consortium will be coordinated by the WHO Registry Platform secretariat, with ongoing monitoring and sharing of deduplication expertise across all Platform participants.

4. **MeSH Coding** – WHO may semi-automatically code the Conditions, Interventions, Primary and Secondary Outcomes fields to MeSH terms to facilitate search and retrieval, perhaps using a consortium of service providers as with trial deduplication. If so, the WHO will offer the MeSH terms back to the registers to help improve each register's own search portal.

5. **Data Interchange Standards** – data from Member and Non-Member Registers must be uploaded to the WHO using a standard XML DTD. This DTD will be adapted from the one used by [clinicaltrials.gov](http://clinicaltrials.gov), with harmonization as much as possible with developing BRIDG and other standards relevant to clinical trial data interchange.
6. **Registry Platform Search Portal** – the WHO plans to build a one-stop search portal searching all Member Registers as well as non-Member registers that upload to the WHO using the interchange standard. The database for the Search Portal will mirror parts of the Reference Database and will offer an open access web services API.
  - A. **Results Reporting Standards** – the current tentative standard for results reporting is at least an English language ICH E3 summary, with the Primary Register ID added and the Conclusions removed. Work on this standard is being deferred until mid-2006, but it remains a top concern of the Registry Platform project.

## 5. Presentations Given by the Secretariat Staff

Several presentations have been given by the Secretariat Staff in the course of the last 6 months to get the project known by as large a spectrum of stakeholders as possible. Please feel free to use these presentations, provided we receive an information note from you on how these will be used and in which context.

List of presentations (in chronological order – most recent at top):

- **Dr. Ida Sim** - Advisory Committee on Health Research (ACHR), 45<sup>th</sup> Session, The World Health Organization, Geneva, Switzerland. 7 November 2005. [Link to Presentation](#)
- **Dr. Ida Sim** - American Medical Informatics Association, Washington D.C., United States of America. 24 October 2005. [Link to Presentation](#)
- **Dr. Ida Sim** - International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Regulatory Policy & Technical Standards Committee, Geneva, Switzerland. 14 October 2005. [Link to Presentation](#)

- **Dr. Patrick Unterlerchner** - The BDA (Biotherapy Development Association) second Alpine meeting "Strategies for Harmonization of Next-Generation Oncology Drug Development", involving senior delegates from Regulatory Authorities, the Pharmaceutical Industry, Patient Advocacy Groups and Academia, Innsbruck, Austria. 5-7 October 2005. [Link to Presentation](#)
- **Dr. Luis Gabriel Cuervo** - Critical Issues In Clinical Trial Registries And Registers: A Focus on Operational Considerations & Transparency, Philadelphia, Pennsylvania, United States of America. 22-23 September 2005. [Link to Presentation](#)
- **Dr. Metin Gülmezoglu** - Annual Conference of the German Epidemiology, Biometry and Medical Informatics Societies, Freiburg, Germany. 14-15 September 2005
- **Dr. Metin Gülmezoglu** - U.S. Institute of Medicine (IOM), Washington D.C., United States of America. 26-28 June 2005

- **Dr. Tikki Pang** - Brainstorming meeting to explore the possibility of establishing an European registry of ongoing clinical trials, Milan, Italy. 30 May 2005. [Link to Presentation](#)
- **Dr. Patrick Unterlerchner** - Symposium on Translational Research for Innovative Infectious Disease Control: From the Laboratory to the Field, The World Health Organization, Geneva, Switzerland. 30 May 2005. [Link to Presentation](#)
- **Dr. Metin Gülmezoglu** - Vienna Initiative to Save European Academic Research, Vienna, Austria. 29-31 May 2005
- **Dr. Metin Gülmezoglu** - International Committee of Medical Journal Editors (ICMJE) Meeting, Washington DC, United States of America, 2-3 May 2005

## 6. Project Timeline

**4th Quarter, 2005** SAG meeting; finalize Trial Registration Data Set and Register Membership criteria; establish a global deduplication process; issue the IT Request for Proposal (RFP).

**1st Quarter, 2006** IAB meeting; Launch Member Register network and deduplication.

**2nd Quarter, 2006** Launch of the Search portal.

**Fall, 2006** 1st Annual Registry Platform Conference on Trial Registration and Reporting, anticipated to take place in Kobe, Japan, hosted by the WHO Kobe Center.

## 7. Contact Us

We welcome your questions, comments and suggestions on any of the topics developed in this Newsletter and on our project in general. Please send your mail to: [ICTRPinfo@who.int](mailto:ICTRPinfo@who.int)

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