WHO International Clinical Trials Registry Platform (ICTRP)

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Statement of New York Workgroup  
(Various Stakeholders, October 2004)

- Need for global approach to clinical trials registration
  - Unambiguous identification of trials
  - Developing consensus on which trials, data, timing and disclosure of results
  - One-stop, publicly available search portal
  - Simple, effective, efficient solutions
  - Building capacity where appropriate

- WHO should establish formal process on a global approach
  - Appropriate governance
  - Collaborative process, involving all interested parties
  - Leveraging existing structures; identifying any need for new structures
  - ICMJE deadline (July 2005: register trials prior to publishing articles)
Ministerial Summit on Health Research
Mexico City, Mexico – November 16-20, 2004

<table>
<thead>
<tr>
<th>Role</th>
<th>Count</th>
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<td>Ministers</td>
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<td>Deputy Ministers</td>
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<td>Head of Delegations</td>
<td>28</td>
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<td><strong>TOTAL</strong></td>
<td><strong>52</strong></td>
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The Ministers of Health and other participants from 52 countries called for action by:

• *All major stakeholders*, facilitated by *WHO secretariat*, to establish a platform linking a network of *international clinical trials registers* to ensure a single point of access and the unambiguous identification of trials.
Report from the Ministerial Summit on Health Research

Includes:
Mexico Statement

- **EB115** (January 2005)
- **WHA58** (May 2005)
May 25, 2005  WHA approved the resolutions emanating from the Mexico Summit Statement on Health Research
It’s not a feeling you can get every day.
Why register?

- Obligation to trial participants, the public
- Increases participation (i.e. patients recruitment; information to doctors, researchers)
- Addresses analysis, reporting and publication biases (ICMJE initiative)
- Contributes to systematic reviews
- Speeds access to results
- Increases effectiveness of research funding
- Impending increase in number of trials
Registers do exist, but....

- Designed for different purposes
- Compliance is low
- Plethora of registers leads to fragmentation
- Systematic reviewers do not/cannot use them
- Not easy to search for all relevant trials
- Also: more registers coming! (i.e. national registers; registers focused on orphan diseases)

Need for consolidation

→ WHO ICTRP
Overall benefits of registration

- Addresses ethical obligations
- Improves access to research information: access to information about ongoing research is crucial to make decisions about future research and policy development
- Enhances transparency and accountability
- Improves equity, ownership and participation
- Improves good research and clinical practice
- Help rebuilding public confidence in science
- Helps in medical diagnosis, treatment and prevention of diseases
Why WHO?

- Global, neutral, independent
- Convening power (i.e. through WHA resolutions)
- Role in setting norms and standards in research, policy and practice
- Contributes to capacity building (i.e. in developing countries)
- Commitment to achieving equity in health
- Political legitimacy, accountable to member states
Key issues*

* Discussed at a WHO Technical Consultation, Geneva, April 25-27, 2005

- Registration standards (i.e. which trials to register; when to register; where to register?)
- Trials characteristics (minimum data set: 20 items)
- Results disclosure standards (i.e. when to disclose results, what to disclose?)
- Role of WHO
Minimum Data Set (I)

1. Unique trial number
2. Trial registration date
3. Secondary identification
4. Funding source(s)
5. Primary sponsor
6. Secondary sponsor(s)
7. Responsible contact person
8. Research contact person
9. Title of study
10. Official scientific title of study
Minimum Data Set (II)

11. Research ethics review
12. Condition
13. Intervention(s)
14. Key inclusion & exclusion criteria
15. Study type
16. Anticipated trial start date
17. Target sample size
18. Recruitment status
19. Primary outcome
20. Key secondary outcomes
Translational Medical Research and the Role of Clinical Trials

**Translational Research**
(Lab)

**Clinical Problem**
(Bedside)

**Medical Investigation**

Clinical Trials help in improving care to patients
(i.e. diagnosis, treatment, and prevention of common diseases and conditions)

Clinical Trials Registry Platform