

**Ottawa Statement on trial
registration:
Principles of operationalisation of
registration of results**

27th October, 2006
Dublin, Ireland

<http://ottawagroup.ohri.ca>

Ottawa Group meeting, Dublin , 27th October, 2006

- Karmela Krleza-Jeric
- An-Wen Chan
- Michael Goodyear
- Ida Sim
- Christian Gluud
- Kay Dickersin
- Jeremy Grimshaw

Ottawa Group meeting, Dublin , 27th October, 2006

Welcome

Thanks

Cochrane colloquium



CIHR for its support

OHRI for hosting our website

all of those that contributed,
signed, promoted, and have
been using the OS

Ottawa Group

- Proposes principles of international of standards for trial registration;
- An independent group of interested stakeholders that sign the Ottawa Statement on trial registration principles;
 - **members** include systematic reviewers, individual researchers, networks and groups, journal editors, consumers, funders, members of ethics boards and of registries.
- <http://ottawagroup.ohri.ca>

- **Participation** in Ottawa group trial registration dialogue is open to both those that signed and those that did not sign the Ottawa Statement.

Ottawa Group

- Trial registration dialogue is led at face-to-face meetings and via Internet:
<http://Ottawagroup.ohri.ca>
- You can endorse the Ottawa Statement directly on our website.

Ottawa Group: Steps in Consensus Building

- <http://ottawagroup.ohri.ca>
- Dialogue on operationalisation:
 - **Ottawa** meeting 4th of Oct 2004 (CC)- **OS1**
 - **Portland** meeting 23rd of May 2005 (SCT),
 - **Melbourne** meeting, 24th of October 2005 (CC)
- **OS2**
 - **Dublin** meeting, 27th October 2006 (CC)

Building of an International Consensus on Trial Registration

- Ottawa meeting in October 2004 hosted by CIHR during the 12th Cochrane Colloquium
 - Objective: To define **principles (part 1) and operationalisation (part 2) of trial registration**
 - **Ottawa Statement on principles of trial registration** - as of Oct 2006 endorsed by more than 120 individuals & groups

Ottawa Statement on Trial Registration

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The Ottawa Statement, Part One: Principles for international registration of protocol information and results from human trials of health-related interventions

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Principles for international registration of protocol information and results from human trials of health related interventions: Ottawa statement (part 1)

Karmela Krleza-Jeric, An-Wen Chan, Kay Dickersin, Ida Sim, Jeremy Grimshaw, Christian Glud and for the Ottawa Group

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Updated information and services can be found at:
<http://bmj.com/cgi/content/full/330/7497/956>

These include:

Data supplement

"Ottawa Group members list and full statement"
<http://bmj.com/cgi/content/full/330/7497/956/DC1>

www.ottawagroup.ohri.ca

<http://ottawagroup.ohri.ca>

Ottawa Statement, Part 1

Key issues

- **All types of trials**
- **Unique ID**
- Definition of minimum **protocol items and results**
- **Timing** of registration and public release of minimum protocol items and results
- **Organisation of registries**
- **Responsibilities** of sponsors, investigators, ethics committees, journal editors

Ottawa Statement, part 2

Principles of operationalisation for international trial registration, a draft

Key issues

- **Unique ID**
- **Minimum protocol items and results**
 - Support the efforts by WHO and ICMJE of registration of all 20 WHO items as necessary but insufficient and
 - Proposed Ottawa group items
- **Characteristics of registries**
- **Search portal**

Ottawa Group: Steps in Consensus Building: Dialogue with others

Dialogue with other major initiatives such as WHO-ICRTP, as well as medical journal editors, ethics committees, and industry.

Several members of the Ottawa Group are actively involved in the WHO project in various capacities.

Ottawa Group Dissemination

- Presentations
- Translations and publications in Japanese, French, Spanish, Chinese;
- Publications: BMJ, Jpn Pharmaceut Ther, PLoS;
- Citations
- <http://ottawagroup.ohri.ca>

Today, 27th October 2006

Dialogue on principles of
operationalisation of ***results
reporting***



Keep in mind: scope is a variable of end user

why and for whom

- potential participants –users – people
- researchers
- systematic reviewers
- funders
- pharma
- journal editors - science
- general public- global knowledge

We shall continue this dialogue

- <http://ottawagroup.ohri.ca>
- *Face to face meetings*

Ottawa Group meeting
Dublin, 27th October 2006

Chair: Karmela Krleza-Jeric