

# Ottawa Statement

## Principles of operationalisation of trial registration

Melbourne 24<sup>rd</sup> of October 2005

@ the Cochrane Colloquium

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<http://ottawagroup.ohri.ca>

# Ottawa Group meeting, Melbourne 24 of October 2005

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

# Ottawa Group meeting, Melbourne, 24 of October 2005

Welcome

Thanks to

Cochrane colloquium



CIHR for its support

OHRI for hosting our website

all of those that contributed,  
signed, promoted, and used the OS

# Ottawa Group

- **Ottawa Group** is an independent group of interested stakeholders, including systematic reviewers, researchers, journal editors, members of ethics boards, consumers, funders, and registries.

<http://ottawagroup.ohri.ca>

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# Participation

in the 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 Statement directly on our website

# Building of an International Consensus on Trial Registration

- Ottawa meeting in October 2004 hosted by CIHR during the 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 2005 endorsed by more than 120 individuals & groups

# Ottawa Statement published in April 2005

Principles for international registration of protocol  
information and results from human trials of health  
related interventions: Ottawa statement (part 1)  
*BMJ* 2005;330:956–9

And it is posted on:  
<http://ottawagroup.ohri.ca>

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# Ottawa Statement, Part 1

## Key issues

- All types of trials included
- Unique ID
- Definition of minimum protocol items and results
- Timing of registration and public release of minimum protocol items and results
- Characteristics of registries (linkage, English language)
- Responsibilities of sponsors, investigators, ethics committees, journal editors

# Ottawa Group: Steps in Consensus Building

- <http://ottawagroup.ohri.ca>

- Dialogue on operationalisation:

**Ottawa** meeting 4<sup>th</sup> of Oct 2004

**Portland** meeting 23rd of May 2005 (SCT),

**Melbourne** meeting, 24rd of October 2005 (CC)

# Ottawa Group: Steps in Consensus Building

Interact & feed into other major initiatives such as WHO-ICRTP & Medical Editors

Promotion, presentations, translation, publications, citations

Translated and published in Japanese; other translations in progress

# Recent PUBLICATIONS

Krleža-Jeric K. [Clinical Trial Registration: The Differing Views of Industry, the WHO, and the Ottawa Group](#) PLoS Medicine. 2005 Oct 18, Vol. 2, No. 11, e378 DOI: 10.1371/journal.pmed.0020378.

Today, 24<sup>rd</sup> October

***Dialogue on principles of trial registration***

***Include virtually those that cannot be with us via our website***

<http://ottawagroup.ohri.ca>

We shall continue this dialogue

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

# Continuation of a dialogue on operationalisation

<http://ottawagroup.ohri.ca>

- *to finalize the list of (optimal) protocol items*
- *to continue a dialogue on trial results*

# Continuation of a dialogue

*issues that will not be discussed today are not forgotten but will be dealt with in future:*

- *Principles of protocol registration and result reporting of small, investigator driven trials; both academic and industry*
- *Negative effects of publish or perish pressure on efforts of de-duplication of publishing of results*
- *Need to deal with proprietary and intellectual rights*
- *Principles of registration and disclosure of results*

# Ottawa Group meeting

## Melbourne 24 October 2005

*Chair: Jeremy Grimshaw*

*Objectives:* To define principles of operationalization for key elements of trial registration:

- Unique ID
- Minimum and optimum protocol items
- Certification criteria for registries
- Search portal
- Trial results