

PORTLAND MEETING

The second meeting of the Ottawa Group was held in Portland, USA on May 23, 2005 during the annual meeting of the Society for Clinical Trials. Over 30 individuals were in attendance, representing researchers, clinicians, journal editors, research ethics boards, and pharmaceutical companies. Attendees discussed the operationalisation of registering and publicly disclosing both protocols and results.

SUMMARY OF DISCUSSION

1. Context

Interests of multiple parties must be considered, including trial participants, patients, researchers, funders, journals, and industry.

2. Registration of protocol items

A preliminary list of required protocol items for registration were proposed and discussed for inclusion in the draft Ottawa Statement, Part 2. These items were compared to those defined by the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (see table). The second International Committee of Medical Journal Editors (ICMJE) statement was released after the meeting and was therefore not discussed; however, it endorsed the WHO list of minimum protocol items.

3. Registration of results

Key issues were discussed:

- Which trials to include
- Which results to report
- Characteristics of reporting
- Timing
- Relationships among registries, journal articles, and results websites

NEXT STEPS

1. The Portland meeting demonstrated that the Ottawa Group should focus on guiding principles rather than the technical details of operationalisation. Part 1 defined the principles of "what" trial registration should entail; Part 2 will now focus on the principles of "how" this should be accomplished.
2. In preparation for the next open dialogue in Melbourne, Australia (October 24, 2005), your input would be greatly valued.
 - a. Please comment on the protocol items proposed by the Ottawa Group in the attached table.

- b. Please communicate whether you agree that the Ottawa Group should endorse the WHO 20-item minimal dataset and the ICMJE statement as a promising initial step in the evolving trial registration process.
3. As the WHO is building global consensus - to which the Ottawa Group has been contributing - please provide comments on the WHO proposed standards for trial registration by visiting: <http://www.who.int/ictrp/en/>