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International Dialogue on the Public Reporting of Clinical Trial Outcome and Results – PROCTOR Meeting

On the 28th and 29th March 2008, the Canadian Institutes of Health Research (CIHR), held a meeting on clinical trial results reporting in Ottawa. The meeting was called PROCTOR, an acronym for the Public Reporting Of Clinical Trials Outcomes and Results.

The current system of reporting trial results requires change. Not all trials get reported and even those that do are often incompletely reported. The growing capacity of technology offers opportunities to complement reporting in traditional peer-reviewed journals with more detailed and widely accessible reporting of research results. The internet also allows data to be translated and packaged in various ways for different user groups.

Identifying that we are at a crucial point for results reporting, CIHR decided to launch an international dialogue of constituencies interested in results reporting, aiming at contributing toward the development of international standards for results disclosure. This dialogue builds on the rich experience gained during the development of Ottawa Statements (*http://ottawagroup.ohri.ca/)* and the World Health Organization International Standards of Trial Registration (*http://www.who.int/ictrp/en/)*, also taking into account the plethora of guidelines and statements from groups such as CONSORT (*www.consort-statement.org)*, the International Committee of Medical Journal Editors (*http://www.icmje.org/clin_trial07.pdf*), and the International Conference on Harmonization (*http://www.ich.org).*

Another reason for holding the meeting at this time was the ongoing implementation of the Food and Drug Administration Amendments Act (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf*) in the USA, which comes into force from September 2008. This is likely to have important international implications, and both CIHR and the meeting participants felt the need to learn from and contribute to its implementation process.

About 20 participants from a wide range of constituencies were invited to enable sharing of views. A unique feature of this meeting was that each constituency was equally represented. Participants prepared for this dialogue by consulting other participant(s) from the same constituency and their networks. For example, consumers were broadly consulted via the Internet. Several invitees who could not attend the meeting also contributed their views, which were incorporated into the presentations. Thus, views were shared among clinicians, trialists, systematic reviewers, consumers, policy makers, journal editors, ethicists, public funders, and pharmaceutical and medical device manufacturers.

In addition to the presentations outlining the views of different constituencies, the meeting learned about technical aspects of results disclosure, including privacy issues.

The rich discussion focused on identifying options and challenges. There was general agreement that it was extremely important to proceed

with international dialogue toward international standards on results reporting.

The ways of achieving this would include opening communication channels with Food and Drug Administration/National Institutes of Health/ClinicalTrials.gov and intergovernmental agencies, involving other relevant groups and exploring various options at the national and international levels.

The meeting did not aim to reach consensus or to publish detailed recommendations from this preliminary discussion, but rather to ensure that all constituencies were given a fair hearing and to publish a report that sets out all the options, identifies areas where there is agreement, and highlights aspects where consensus has yet to be reached. The meeting discussed possible next steps, including a Delphi panel, an open conference on results reporting, and supporting initiatives likely to encourage universal results reporting.

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