

DEPARTMENT OF RESEARCH POLICY AND COOPERATION

INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM

**Formal Consultation on Disclosure Timing
Geneva, Switzerland, 26 April 2006**

Summary

Introduction

The WHO Registry Platform conducted an extensive consultative process over the past year to address the issue of disclosure timing of registered trial information. On 26 April 2006, a Formal Consultation was held to facilitate discussion in an atmosphere of mutual trust and respect among a broad spectrum of stakeholders in clinical trials. The purpose of the Formal Consultation was to inform the Registry Platform Secretariat regarding the specific issue of disclosure timing for registered data items. The participants did not constitute a decision-making body.

In order to ensure open, honest, and frank discussion, the consultation was conducted under the *Chatham House Rules* – the views expressed in the room could be discussed and described after the meeting, but should not be attributed to any specific individual or group.

The Formal Consultation

A total of 68 participants attended the Formal Consultation, moderated by Dr Norman Swan. Attendees represented a variety of constituencies:

Academia	9
Ethics committees	3
Government	3
Industry (pharmaceutical, biotechnological, devices)	21
Law	1
Medical journal editors	4
Non-governmental organizations	2
Patient organizations	8
Trial registers	4
Sub-total	55
Moderator	1
WHO participants	7
WHO Registry Platform Secretariat	5
Grand Total	68

The meeting began with short presentations by representatives from the Registry Platform Secretariat, the chair of the Registry Platform's International Advisory Board, medical journals, the pharmaceutical industry, and patient groups. An open, highly-informative discussion was then moderated by Dr Swan. A variety of perspectives were presented regarding the following key issues:

- The benefits and problems of immediate public disclosure of intervention names and novel outcomes for registered trials
- The benefits and problems with registering early uncontrolled trials
- The feasibility of implementing a reliable delay mechanism
- The importance of compliance mechanisms

The specific views expressed during the meeting are not summarized here, as a synopsis could not adequately reflect the detailed content, context, and meaning of the spirited discussion.

Taking into account the informative views expressed at the Formal Consultation and throughout the preceding consultative process, a Disclosure Timing policy has been developed by the Registry Platform Secretariat and was announced on 19 May 2006 during International Clinical Trials' Day events in Brussels, Belgium.

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(in alphabetical order – 68 in total)

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