WHO Technical Consultation on Clinical Trials Registration Standards

25-27 April 2005

WHO Headquarters, Geneva, Switzerland

The text in *italics* indicates items not discussed in detail and explicitly agreed by the whole group. However, there were no major disagreements on these and many participants support their inclusion in the meeting conclusions.

I. Background

The World Health Organization (WHO), based on a consensus developed by a broad variety of stakeholders, is now establishing an *International Clinical Trials Registry Platform* project (ICTRP), which aims to facilitate access to information about clinical trials and their results.

A series of technical consultations with various stakeholders took place in 2004 and led to a strong support at the Ministerial Summit in Mexico City[1] for WHO to lead an Initiative on trial registration and disclosure of results.

The technical consultation on clinical trial registration standards held on 25-27 April 2005 focused exclusively on the elaboration of registration standards. The central part of the meeting were the plenary discussions for a common agreement on the outcomes of the four working groups, which objectives were to reach consensus on:

- **GROUP 1**: Registration Standards (Which trials to register)
- **GROUP 2**: Trials Characteristics (Minimum data set)
- **GROUP 3**: Results Disclosure Standards
- **GROUP 4**: Where to Register and WHO Role

Each group was given an objective and a task and was asked to formulate recommendations for discussion at the plenary session.

II. Outcomes of the Consultation

Note: These are currently presented as agreed during the meeting and should be regarded as "draft". The Secretariat is collecting comments and will work with the participants to operationalize these agreements.

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[1] 16-20 November 2004, Mexico City, Mexico

- ## GROUP 1: Registration Standards

Objective: to define registration modalities.

Task: to discuss the basic standards for trial registration and make specific recommendations.

Questions: Which trials to register? When to register a trial?

Group 1 came to the following conclusions:

Which trials to register?

Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes should be registered.

- Trials aimed to assess all health and health care interventions, not only medicines and medical devices, should be registered.
- The intent of the definition above is to include trials that could inform health and health care practice.
- Exploratory studies that are not designed to influence health practice and that serve only to set direction for future testing need not be registered.
- When trial sponsors are unsure whether to register or not registration is recommended.

When to register a trial?

- *Trials should be registered as early as possible, ideally before recruitment of the first participant.*
- *The informed consent form should include a trial identification number.*

- ## GROUP 2: Trials Characteristics

Objective: to achieve a clear description of the "minimum data set" together with additional optional information.

Task: make specific recommendations on a set of trial descriptors (including unambiguous trial identification)

Questions: Which items to include in the minimum data set? What are the basic requirements?

In answering the question **"Which items to include in the minimum data set?"**, the following list has developed (see next page):

	Item	
1.	Unique trial number	
2.	Trial registration date	
3.	Secondary IDs	
4.	Funding source(s)	
5.	Primary sponsor	
6.	Secondary sponsor(s)	
7.	Responsible contact person	Public contact
8.	Research contact person	Principal investigator
9.	Title of the study	Brief title
10.	Official scientific title of the study	intervention for condition on outcome
11.	Research ethics review	Yes / No
12.	Condition	
13.	Intervention(s)	Including intervention duration
14.	Key inclusion and exclusion criteria	
15.	Study type	Select from list (currently available in the clinicaltrials.gov register)
16.	Anticipated trial start date	Estimated enrolment of the first participant
17.	Target sample size	
18.	Recruitment status	Is this information available yes/no. if yes, link to information
19.	Primary outcome	Include time of measurement or time to completion
20.	Key secondary outcomes	

As for the second question, "**What are the basic requirements for a minimum data set?**", the plenary discussion concluded the following to be mentioned together with data items above:

- All minimum data set information should be reported in English.
- All items listed above should be included in the minimum data set on scientific and ethical grounds. Therefore, all fields in the minimum data set should normally be entered into the register at the time of trial registration.
- However, one or more of data items 10, 13, 17, 19, 20 may be regarded as sensitive for competitive reasons by the sponsor who may wish to delay release of the information.
- In any event all data items should be made publicly available by agreed dates.
- WHO will convene a group to develop a mechanism to advise on requests to delay release of one or more of data items until a requested date.

- **GROUP 3: Results Disclosure Standards**

Objective: Identify how trial results are disclosed, what can be disclosed and when.

Task:
1. Recommend standards on when, what to disclose, for which trials and where to disclose (at principle level)
2. Describe areas of disagreement (if they persist for possible working group task)

Questions: What to disclose? What are the register/Database characteristics? Who does what?

Group 3 presented the following:

- *Assume the results database is an extension of the trial register.*
- *Complement and not replace peer-reviewed publications. Results disclosure should not be a barrier to peer-review journal publication.*
- *Results database will be useful for multiple constituencies (systematic reviewers, patients, policy-makers).*
- *While there is no single agreed definition of study completion the results should be disclosed within one year of completion as a general standard. Results of trials of commercially developed drugs (? newly registered drugs) should be disclosed within one year of first product launch?*

The following questions where also answered

What is disclosed?

- *Use ICH E3 synopsis as template*
- *BUT add trial register number AND remove 'conclusions' heading.*

Register / database characteristics

- *Results linked to trial register (if not at the same location)*
- *Open access*
- *English summary*

Who does what?

- *Sponsor/ funder is responsible for ensuring results are disclosed*
- *For unfunded trials, primary investigator takes responsibility*
- *For marketed products, license holder is responsible for updates*

- **GROUP 4: Where to Register and WHO Role**

Objective: Define characteristics of a register that is internationally acceptable. Identify how WHO can contribute to global access.

Task:
1. List the essential and desired characteristics of register(s) that would satisfy journal editors' position and establish international standards
2. Advise on additional functions or requirements that could be addressed by WHO or other partners internationally.

Questions: What are the characteristics of a register?

Group 4 presented the following:

1. *Open access minimum data set without barriers*
2. *Searchable by standard electronic (internet-based) methods*
3. *Open to all prospective registrants free of charge or at minimal cost, with mechanisms to ensure that fee is not a barrier*
4. *Validates registered information*
    - *Responsibility of registrant to confirm accuracy of data*
    - *Register follows written standard operating procedures (e.g., method to confirm trial is not already registered on registry)*
5. *Identifies trials with a unique number*
    - *Collaboration among registers necessary for unambiguous trial identification*
6. *States whether register is updated or not*
7. *Do not consider no- for-profit or for-profit distinction as a register standard issue (as long as the integrity of display is maintained, i.e. no marketing or misleading additions)*
8. *Other issues for discussion: make minimum data set available in English in addition to other languages of country, sustainability of register records over long term*

Group 4 discussion was limited to the register characteristics.