

Ottawa Statement Part 2

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These comments are based on the Nov 17, 2005 draft

- I support the initial reminders of the principle at the beginning of each section
- 2.2 (p. 1, Table) specify what a “secondary ID” means (may be we need a glossary with clear definitions, for the whole Ottawa statement)
- 2.2 (p. 1, Table) The global body to assign IDs (e.g., WHO) may also be financed by a fee contribution for each registration (depending of the economical status of the country where the trial is to be conducted and of the sponsor(s) various fees may be used)
- 2.3.3 I agree that WHO may be a natural body, however WHO may sometimes be seen as bureaucratic organization and have a not so positive image
- 3.5.1. I support the view that the 20 item WHO list is an insufficient minimum; we should however be fully aware that it will most difficult to make the longer Ottawa statement list be accepted ...
- 3.6. Clear definitions of the items should be given (e.g. secondary ID, secondary sponsor)
- 3.6.12. Short lay description: I proposed a structured format (e.g., problem to be solved, clinical question, objectives, hypotheses, rationale for the method chosen)
- 3.6.21-23. Add type of setting?
- 3.6.26.2 Why not a list of who / which part is blinded (1. patient, 2. professional in charge of the intervention, 3. measurement of outcome, 4. analyses of data)
- 3.x Additional items to be developed? Unclear for some of them.
- 4.3.2. Certification of registry, it is crucial, which should be the certifying body?
- 4.3.2 An updated list of certified registries should be made available, with electronic links to each specific website – one can imagine common names for the various country, for instance, specific registry websites.
- 4.4 There may also be domain specific or theme registries (e.g., cancer, prevention,...)

- May we imagine mandatory core items and optional items (at least in the beginning and a sort of more plausible alternative?)
- We should also envision a policy of how to promote, lobbying, enforce the Ottawa statement

I have already endorsed the Ottawa statement Part 1, and I declare herewith to endorse Part 2 as well.

Best wishes.

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