

Perinatal Trials Toolkit

Registration of clinical trials

Which trials should be registered?

According to the Australian Clinical Trials Registry (ACTR) “all clinical trials involving Australian investigators or participants, in all areas of health and testing all forms of interventions should be registered” (ACTR, n.d.).

Trials that meet the International Committee of Medical Journal Editors (ICMJE) definition of clinical trial should be registered prior to commencement. That is, any research that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include any intervention used to modify a health outcome and include drugs, surgical procedures, devices, behavioural treatments.

Are any trials excluded from the requirement to register?

ICMJE states that among the trials that meet the above definition, some may be clearly excluded or included.

Exclusion from the registration requirement is accepted if the primary goal of the clinical trial is to assess major unknown toxicity or determine pharmacokinetics (phase 1 trials).

Inclusion on registry is mandatory for all trials whose primary purpose is to affect clinical practice (phase 3 trials). Others are not so clear. ICMJE states that between the “two extremes are some clinical trials whose prespecified goal is to investigate the biology of disease or to provide preliminary data that may lead to larger, clinically directive trials”(De Angelis, 2005).

What is an approved registry according to ICMJE?

The ACTR is consistent with the WHO requirements set out by the ICMJE. The ICMJE has stated that they do not promote one registry but its member journals will require authors to register their trial in a registry that meets several criteria. WHO require that a register should be electronically searchable and accessible to the public at no charge. It must be open to all registrants and not for profit and must have a mechanism to ensure the validity of the registration data.

Checklist for trial registration

If you can answer yes to any of the following questions, registration of the trial in the ACTR is recommended:

- Is this a phase 2, 3 or 4 clinical trial?
- Does the study involve prospectively assigning human subjects to intervention and comparison groups evaluating a cause-and-effect relationship between a medical intervention and a health outcome?
- Are you in doubt whether your trial meets the criteria for registration?



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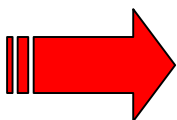
Registration of trials addresses the problem of publication bias. Publication bias refers to the phenomenon whereby the results of some randomised controlled trials are not published or only selected results of the trial are reported. So, for example, trials that don't show a positive result may not be published, or if the findings are not consistent with the aims of the trialists they may not seek publication. If investigators don't set out their hypotheses at the beginning, there may be the tendency to data dredge until they find something. This can all cause 'bias' in publications and may alter what is the 'evidence for practice'. This may impact on what is really best clinical practice according to the evidence.

If trials are registered prior to commencement (so that the trial protocol is registered), then investigators must set out their hypothesis at the beginning, must think clearly about the best way to analyse the results, and will invest more energy in insuring that studies are robust and that findings are released.

Weblinks

Australian Clinical Trial Registry
<http://www.actr.org.au/>

International Clinical Trials Registry Platform (ICTRP)
http://www.who.int/ictrp/data_set/en/index1.html



For assistance with trial registration please contact your WOMBAT Regional Coordinator or the WOMBAT National Coordinator

This toolkit was prepared by Vicki Flenady, Kate Levett, Karen New and Rebecca Tooher.

References:

- ACTR, n.d. Australian Clinical Trials Registry, viewed 15 July 2007, <<http://actr.org.au/faq.aspx>>.
- De Angelis C. Is this clinical trial fully registered? A statement from the International Committee of Medical Journal Editors. *Lancet* 2005; 365: 1827 - 1829.
- De Angelis C. 'Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *Lancet* 2004; 364:911 - 912.

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