7.5: Trial registration

Until relatively recently, there were no comprehensive sources of information about ongoing clinical trials. Not infrequently, trials would be started and would be prematurely ended with knowledge of their conduct known only to those closely associated with the trial if the findings were not published in the medical literature. Other trials were completed, but their results were never reported for various reasons, including that the investigators or sponsors did not like the findings of the trial! Other investigators might start a new trial, ignorant of the fact that a trial addressing essentially the same question was already under way or had even been completed but not yet published. Those conducting systematic reviews (see Chapter 3, Section 2) would be aware of the published literature but would be ignorant of such unpublished trials. It has been well documented that trials that show a ‘positive’ outcome are more likely to be published than those that do not, and thus the published literature may constitute a biased sample of all of the evidence related to the effects of a specific intervention.

In the 1990s, it was proposed that registers should be set up, in which those conducting trials should be required to record their trial before the first participant was enrolled into it. The record should consist of basic information about the trial (Box 7.3). This recommendation was given teeth in 2005 when the International Committee of Medical Journal Editors (ICMJE), which comprises the editors of many of the major journals that publish papers on the results of trials, made it a requirement for publishing that the trial should have been properly reported to a public clinical trials register before any participant was enrolled into the trial (<http://www.icmje.org>). Initially, the requirement covered only randomized clinical trials, but it has been subsequently expanded to include ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes’, so that Phases I and II trials and non-randomized intervention studies, as well as Phase III RCTs, are included.

Several coordinated trial registries have been set up, so that any individual trial is issued a unique number which is recorded in the International Standard Randomised Controlled Trial Number Register (<www.controlled-trials.com/...>
Trials are only eligible for publication by ICMJE journals if they have been registered in one of the following registries:

- [http://www.anzctr.org.au](http://www.anzctr.org.au)
- [http://clinicaltrials.gov](http://clinicaltrials.gov)
- [www.isrctn.org](http://www.isrctn.org)
- [http://www.umin.ac.jp/ctr/index.htm](http://www.umin.ac.jp/ctr/index.htm)
- [eudract.ema.europa.eu](http://eudract.ema.europa.eu) (new registrations after 20 June 2011), or
- any of the primary registries that participate in the WHO International Clinical Trials Portal (see [http://www.who.int/ictrp/network/primary/en/index.html](http://www.who.int/ictrp/network/primary/en/index.html)). This includes the Pan African Clinical Trials Registry ([www.pactr.org](http://www.pactr.org)). This registry enables African trial registration for those who do not have reliable access to the Internet.

**Box 7.3 (Minimal) information that is required when registering a clinical trial**

- Title of the trial.
- Acronym for the trial (if there is one).
- Study hypothesis/trial objective, i.e. what question(s) is the trial design to address.
- Ethics committee approval—which committees and when approved
- Study design—individual or cluster, whether or not randomized, double-blind, etc.
- Countries of recruitment.
- Disease/condition/study domain—nature of study population and diseases of interest.
- Inclusion criteria for participation in trial.
- Exclusion criteria for participation in trial.
- Anticipated trial start date.
- Anticipated trial end date.
- Current status of trial—ongoing, waiting ethics approval, etc.
- Patient information material—is information about the trial publicly available and where?
- Target number of participants.
- Description of the interventions (for example, name, dose, duration).
- Primary outcome measures.
- Secondary outcome measures.
- Sources of funding.
- Trial website (if there is one).
- Publications.
- Name and contact details for PI and, where different, of person(s) responsible for providing information about the trial to the public and the scientific community.
- Name and contact details for sponsor.