Medical research can be seriously compromised by the selective publication of clinical trial results. Therefore, it is imperative that information regarding clinical trials be available to the general public.

We require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial that starts enrollment after January 1, 2006. For trials that began enrollment before this date, we require registration by April 1, 2006, before considering the trial for publication.

We define a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies that are designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase 1 trials) are exempt.

We do not advocate one particular registry, but registration must be with a registry that meets the following minimum criteria:

- Accessible to the public at no charge;
- Searchable by standard, electronic (internet-based) methods;
- Open to all prospective registrants free of charge or at minimal cost;
- Validates registered information;
- Identifies trials with a unique number;
- Includes information on the investigator(s), research question or hypothesis, methods, intervention and comparisons, eligibility criteria, primary and secondary outcomes measured, date of registration, anticipated or actual start date, anticipated or actual date of last follow-up, target number of subjects, status (anticipated, ongoing, or closed), and funding source(s)

Registries that currently meet these criteria include:

- The registry sponsored by the U.S. National Library of Medicine (www.clinicaltrials.gov);
- The International Standard Randomized Controlled Trial Number registry (www.controlled-trials.com);
- The Cochrane Renal Group registry (www.cochrane-renal.org/trialsubmissionform.php);
- The National (UK) Research Register (www.update-software.com/national/);
- European Clinical Trials Database (http://eudract.emea.eu.int)/.

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Correction


In this editorial from the April 2005 issue of JASN, there was an error in listing the web site URL for the International Standard Randomized Controlled Trial Number registry.

The correct URL is www.controlled-trials.com. The publisher regrets this error.

Related Editorial


Dr. Vivette D’Agati commented on the report by Neal et al., found in the May issue of JASN, in an editorial that appears in the same issue (D’Agati V: And You Thought the Age of Anatomic Discovery Was Over. J Am Soc Nephrol 16: 1166–1168, 2005). The article by Neal et al. did not include the usual reference to this related editorial. The publisher regrets this oversight.