Journal Editors (ICMJE) that clinical trials be prospectively registered, before commencement,[1] is an important step, but of equal or greater importance would be better regulation of trial data and their handling before publication.

Typically, a pharmaceutical company or its hired agent, such as a contract research organization, maintains all of the data collected during a trial. The analysis of the data and its statistical evaluation are generally performed by the company's statisticians. Even principal investigators are not usually privy to this information.

I propose the creation of a third-party organization, independent of the clinical trial sponsor, to perform the vital role of keeper of the trial database, as well as the data analysis according to the primary and secondary trial outcomes specified at the outset. Too expensive, some might say. However, funds are already being paid by the sponsor to have these same tasks done by employees within the company or by a contract research organization. Others might argue that this requirement would represent undue hardship for a company that is making a huge investment to develop its product and hopefully take it to market. This hardship would be lessened if it was applied uniformly to all major clinical trials. If the ultimate objective is to improve the lives of our patients, then the fidelity of clinical trial information is of paramount importance.

A clinical trial registry only provides transparency in terms of the existence of a trial. Third-party handling of trial data and their analysis will ensure transparent evaluation and reporting of the results. We need to enter an era wherein a high-quality trial is evaluated independent of those with a direct financial interest in its outcome.

Vince Bain
Director
Liver Unit
University of Alberta
Edmonton, Alta.

Reference

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2004;171(6):606-7.

DOI:10.1503/cmaj.1041674

Bravo to the International Committee of Medical Journal Editors (ICMJE)! Registration of clinical trials in a publicly accessible registry as a prerequisite for publication[1] is a welcome step beyond the current voluntary registration. This requirement could be strengthened by expanding its application beyond the journals represented on the ICMJE, all of which are either general or internal medicine journals. For example, most clinical trials dealing with child and mental health issues are published in pediatrics and psychiatry journals, which are not represented on the ICMJE, but publication bias is undoubtedly a concern to the editors of these journals as well.

I strongly encourage the ICMJE to enlist the support of major journals in other branches of medicine (such as pediatrics, psychiatry, obstetrics and gynecology, surgery, family practice and emergency medicine) and to lobby government agencies responsible for licensing drugs (e.g., the Therapeutic Products Directorate of Health Canada) to require such registration for, at the very least, phase III clinical trials.

John C. LeBlanc
Assistant Professor
Dalhousie University
Halifax, NS

Reference

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2004;171(6):606-7.

DOI:10.1503/cmaj.1041532

The editors of *CMAJ*, 10 other journals and MEDLINE recently announced that, starting in 2005, they will publish only clinical trials that were registered at inception.[1] Two reasons are offered for this decision: first, the widespread practice of concealing the results of trials with unfavourable results distorts the evidence base, and second, patients volunteering for clinical trials deserve to know that their contribution to improving human health will be available to inform health care decisions, and this knowledge ought to be accessible to everyone. It appears, then, that pharmaceutical companies have an ethical as well as a scientific responsibility to register their clinical trials.

It seems to us that many patients do participate in clinical trials for altruistic reasons; moreover, the consent forms they sign usually appeal, either explicitly or implicitly, to this motivation. If pharmaceutical companies have an ethical responsibility to register the clinical trials for which they seek patients as participants, should not institutional review boards require registration of large clinical trials as a condition of ethical acceptability? Have any institutional review boards taken a position on this subject?

L. John Hoffer
Associate Chair
Jack Mendelson
Chair
Research Ethics Committee
Jewish General Hospital
Montréal, Que.

Reference

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors [editorial]. *CMAJ* 2004;171(6):606-7.

DOI:10.1503/cmaj.1041673

Correction

The DOI published in a recent News item[1] was mistakenly listed as 10.1503/cmaj.1050134. It should have been read 10.1503/cmaj .050134.

Reference

1. Sibbald B. Feeling the pressure. *CMAJ* 2005;172 (6):735.

DOI:10.1503/cmaj.050305