Next steps in trial registration

Minimum criteria have been agreed, and intentions restated

Last year medical journals responded to the growing clamour for greater transparency in the conduct of clinical trials by deciding to require registration of trials that are submitted for publication.1 Various groups have proposed criteria to clarify the implementation of this policy.2,3 These moves have received a mostly positive response from the public, regulators, and industry. Associations of pharmaceutical companies have signalled their support for registration of trials and recording of results although, regrettably, registration will only be voluntary.4 Individual pharmaceutical companies have announced their own initiatives, albeit under pressure from lawmakers and the needs of the market.5

Now the International Committee of Medical Journal Editors (ICMJE) has announced further guidance on trial registration.6 In essence, the guidance restates that trials that begin enrolling patients from 1 July 2005 must be registered in a public trials registry—at or before the onset of enrolment—to be considered for publication in the journals edited by members of the committee. In addition, trials that began enrolling patients before 1 July 2005 must register before 13 September 2005 to be considered for publication. This is also the BMJ’s policy.1,7

The latest guidance from the ICMJE outlines the information that investigators of trials will need to make available to the public, and this minimum dataset has 20 fields. All trialists will have to disclose all of this information to be considered for publication in the BMJ. Pharmaceutical companies regard some of this information to be commercially sensitive, particularly for trials that, as the ICMJE puts it, are designed to “investigate the biology of disease or to provide preliminary data that may lead to larger, clinically directive trials.” Journal editors are given discretion by the ICMJE to consider trials for publication that are in this category and unregistered. The BMJ does not expect to allow any exceptions because we seek to publish only those trials that will influence clinical practice.

The BMJ has not signed the ICMJE’s latest statement because we still disagree with the committee’s policy on one issue that prevented us from signing the previous version. According to the statement, both public ownership and not for profit status are essential for a suitable trial registry. Our view is that, although public ownership is valuable and use of publicly owned registries is to be encouraged, this stipulation is unnecessarily restrictive and should not be an essential criterion. The emphasis, we argue, should remain on registered information being publicly and freely accessible. In addition, to be suitable a registry should identify trials with a unique identifier, the information should be searchable and include all 20 fields, registration should be free or minimal cost so as not to exclude researchers from poorer countries, and the information in the registry should be validated.

We are encouraged that the World Health Organization is bringing stakeholders together to agree on the next steps in this process, and that it plans an initiative to certify registries that meet these agreed standards, in particular to ensure that the information in those registries is reliable and that individual trials can be identified via an international numbering system.7 Within a year WHO intends to provide a web based portal to all these certified registries. As the ICMJE statement rightly implies, it will be at least two years before we know whether this move by journal editors is a success or failure.

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Competing interests: FG attended the meeting of the ICMJE where the statement on trial registration was discussed. She was formerly editorial director of Current Controlled Trials and helped create its clinical trials registry.

7 Advice to contributors. bmj.bmjjournals.com/advice/article_submission.shtml