Welcome

initiative

The decision taken recently by the editors of 11 Indian biomedical journals to publish only
the results of human clinical trials that have
been registered is laudable considering that
India has become one of the most favoured countries for conducting such trials and that more and more papers are published in Indian journals. The move is particularly significant in the context of the disturbing tendency of pharmaceutical companies to manipulate the results of human clinical trials for securing publi-cation and drug approval. One way of ensuring greater transparency is to require prior enrolment of trials in public registries. Even here, as the International Com-mittee of Medical Journal Editors (ICMJE) - a 12-member group — found, the requirement will make little difference as long as it remained voluntary. The ICMJE's decision in 2005 to make registration a pre-condition for publishing the results of clinical trials did the trick, with one registry alone reporting a 73 per cent rise in the number of entries within five months. In 2007, the British Medical Journal editorially noted that the weekly enrolment with ClinicalTrials.gov reg-istry exceeded 200. The success of this initiative has had a cascading effect, prompting more and more jour-nals to follow suit.
Under the new regime evolved by the Indian editors, for the results to be considered for publication in the 11 journals after January 2010, the trials that are to com-mence after June 2008 should be registered prospec-tively and the earlier ones retrospectively. What facilitated these editors to take a firm and definitive position on this issue is that the Indian Council of Medical Research had launched in 2007 an Indian

registry that is linked to the World Health Organisa: tion's International Clinical Trial Registry Platform (ICTRP) - a tie-up that made it an ICMJE-acceptable platform for companies and research institutions-While the editors have done the right thing by not insisting on registration with any particular registry, they appear to have been rather too lenient in the matter of implementation. The 18-month notice they have given for enforcing the decision means the results of trials already under way may well get published much before the January 2010 deadline. The Indian editors' initiative may help in prodding the pharma-ceutical companies to get the clinical trials they un-dertake registered. But this will not solve the problem. The United States has made registration of trials and submission of results mandatory. The need of the hour for India is to adopt a similar legislation to minimise the chances of data manipulation.

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