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Editorial

Registering Clinical Trials

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Patient trust and altruism are crucial to the conduct of research involving human subjects (1). Patients volunteer to be subjects for clinical studies because they believe that the results will benefit other patients. When the results of clinical trials are published, this is true. Indeed, clinical trials are crucial for advancing the quality of medicine because they provide the scientific evidence that supports sound clinical decision-making. For this contribution to the advancement of medicine, we owe our patients our gratitude. We also have an obligation to ensure that their participation makes a difference.

Unfortunately, not all clinical trials are published. Although investigators have an obligation to perform research ethically, and report the findings honestly, there are a number of factors that may determine whether or not the results of a clinical trial are ever published. Studies that provide equivocal or negative results may not be deemed suitable for publication by authors, editorial boards, and sponsors. But, the selective reporting of study results may do a disservice to our patients and violate their trust. Moreover, this may put future patient-subjects at needless risk because other investigators may unknowingly repeat studies that were completed, but not reported.

What does this mean to interventional pain management? As readers of recent guidelines and systematic reviews published in Pain Physician know, a single trial does not usually change the way we practice medicine. Rather, it is the accumulated body of evidence that guides and changes the way we practice. However, selective reporting of results can adversely affect the validity of guidelines and reviews, because unpublished studies cannot influence medical thinking. This can have negative consequences in terms of medical policy-making, including access to medical care and insurance coverage for patients.

One remedy for the problem of selective reporting is to require that all clinical trials be registered with some agency or reporting body, with the database available to all interested parties, including patients. As noted in a statement by the International Committee of Medical Journal Editors ICMJE (1), a clinical trials registry should be accessible to the public at no charge, be available to all investigators wishing to register, be managed by a nonprofit entity, and be searchable electronically. In addition, the registry should record specific types of information, including the study hypothesis and design, informed consent, outcomes measures, eligibility criteria, dates of the study, numbers of participants, funding sources and principal investigator contact information.

For purposes of registration, the ICMJE defined 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" (1). Their revised definition included a requirement that there be a prospectively designated control or comparison group (2). Other types of studies, such as pharmacokinetics and toxicity studies, observational studies with no concurrent control or comparative group, and Phase 1 studies are currently exempt from the need to register. However, any prospective trial whose chief purpose is to affect clinical practice should most likely be registered. Pain Physician has adopted this policy, which will be reviewed over the course of the next 24 months.

To be considered for publication in Pain Physician, the authors of a clinical trial must provide evidence of registration with a public trials registry. Trials must be registered at or before the onset of patient enrollment. This policy applies to any clinical trial beginning enrollment after July 1, 2005. For trials that started before this date, the Pain Physician journal will require registration by September 15, 2005. Although there may be some exceptions to this policy, arguments for exemption must be presented to the editorial board.

Benefits that may accrue from the registration of clinical trials include improved patient understanding about studies being done that may affect their medical care, and increased confidence that their contributions will be worthwhile. Clinicians also will have access to this information, which may improve their participation in the research process. Undeniably, we all have a stake in improving the quality of evidence-based medicine. Moreover, editors of journals will have to abide by the new requirements. Perhaps one result will be that more studies with negative or inconclusive results will be published.

The reasons for requiring registration of clinical trials are to protect the public trust and improve the quality of evidence-based medicine. We support this step forward.

For information about the topic of clinical trials, please see: http:

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//www.clinicaltrials.gov. To learn about registering a clinical trial, see: http://prsinfo.clinicaltrials.gov. Web shots for both sites are shown in Figures 1 and 2. Examples of data collected in the ClinicalTrials.gov registry are shown in Table 1.

Table 1. ***Example of data collected in the ClinicalTrials.gov registry***

1. Titles and Background Information
2. Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information
3. Human Subjects Review
4. Sponsors
5. Study Description
6. Status - Study Phase
7. Study Design
8. Interventions
9. Conditions and Keyword
10. Eligibility
11. Protocol Location, Contact and Investigator Information
12. Related Information

Full descriptions are available at: http://prsinfo.clinicaltrials.gov. PRS users provide and maintain information about their clinical trials ensuring the protocol records are correct and updated in a timely manner. The system allows users to create, modify, maintain and submit protocol records to *ClinicalTrials.gov*.

References

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2. De Angelis C, Drazen JF, Frizelle FA, Haug C, Hoey J, Horton R, Kotzin S, Laine C, Marusic A, Overbeke AJPM, Schroeder TV, Sox HC, Van Der Weyden, MB. Is This Clinical Trial Fully Registered? A Statement From the International Committee of Medical Journal Editors. *JAMA* 2005; 293:2927-2929.

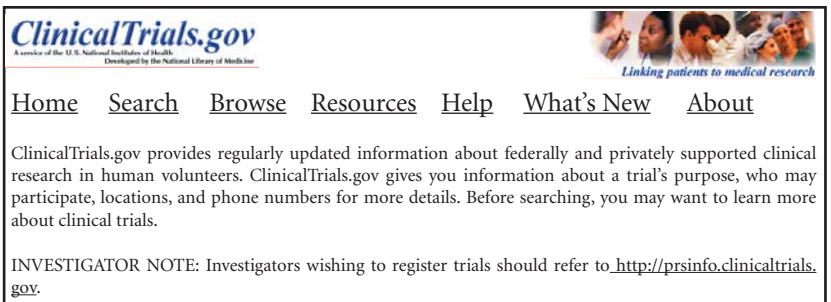

Fig. 1. Web site for topic of clinical trials: www.clinicaltrials.gov

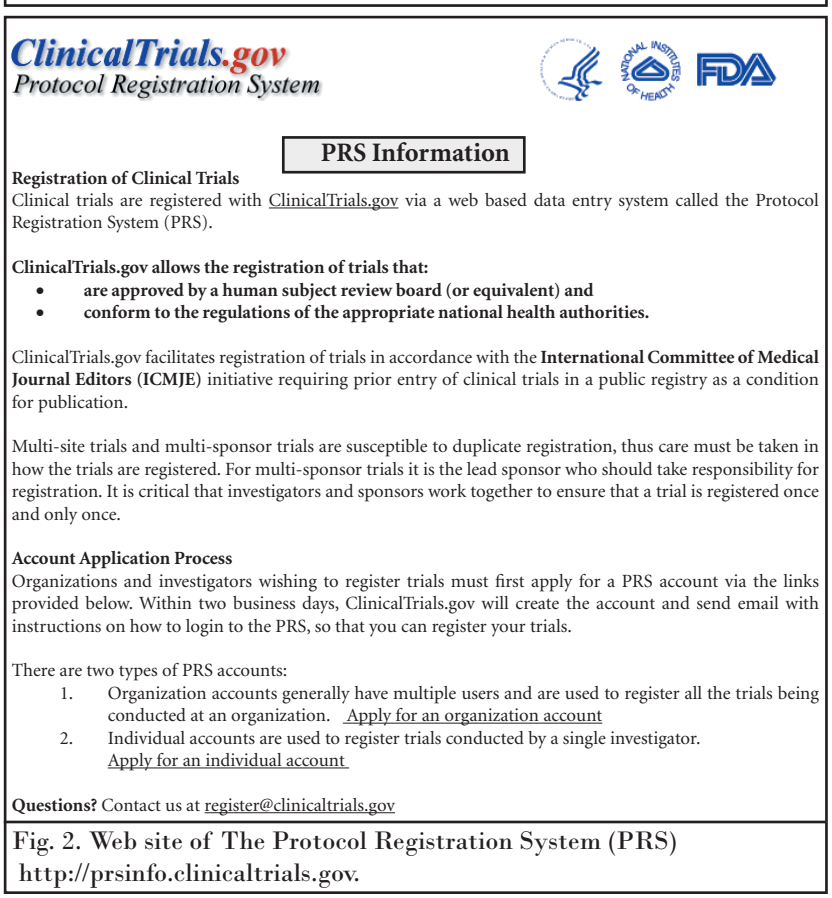

Fig. 2. Web site of The Protocol Registration System (PRS) http://prsinfo.clinicaltrials.gov.