How do I register my trial?

- **Does the trial sponsor have an existing account with the Protocol Registration System (PRS)?** The PRS is a Web-based data system that allows sponsors to submit, maintain, and update information about their trials free of charge. To find out if the sponsor already has a PRS account, check the list at: http://prsinfo.clinicaltrials.gov/prs_organizations.html.
  - **If "yes,"** obtain contact information at: http://prsinfo.clinicaltrials.gov/contactRequest.html.
  - **If "no,"** apply for an account at: http://prsinfo.clinicaltrials.gov/application.html.
- **After you receive login information,** log into the PRS system. (See http://prsinfo.clinicaltrials.gov/intro.html for a guided tour.)
- **View the "Quick Start Guide."** All the features required to enter data about a trial are available through the "Standard Functions" menu.
- **Complete all ClinicalTrials.gov data elements,** providing as much accurate, up-to-date information as possible.
- **After you enter the data,** a PRS administrator will review the record before releasing it for publication on the ClinicalTrials.gov site.
- **You can view a record,** including its unique identifier (NCT number), at ClinicalTrials.gov within 2–5 business days after it is released.

For more information about registering a clinical trial at ClinicalTrials.gov, see the FAQs at http://prsinfo.clinicaltrials.gov or send e-mail to register@clinicaltrials.gov.

Resources

Information on Registering Clinical Trials
http://prsinfo.ClinicalTrials.gov

ClinicalTrials.gov Web Site
http://www.ClinicalTrials.gov

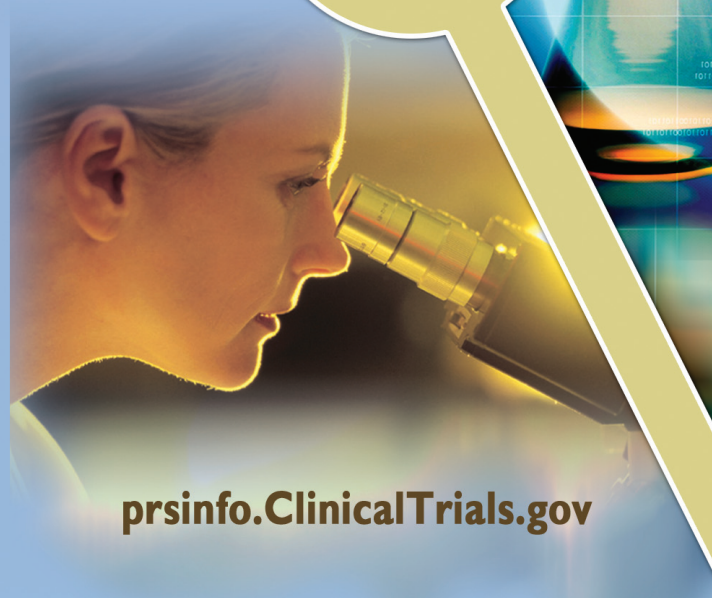
The International Committee of Medical Journal Editors (ICMJE) policy on trial registration
http://www.icmje.org/clin_trialup.htm

Food and Drug Administration's Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions
http://www.fda.gov/cder/guidance/4856fnl.htm

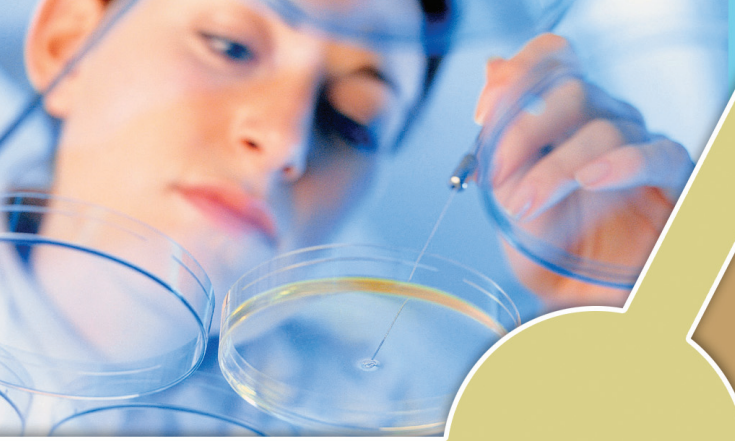
Registering Clinical Trials

with ClinicalTrials.gov

Linking Patients to Medical Research



prsinfo.ClinicalTrials.gov



What is ClinicalTrials.gov?

ClinicalTrials.gov is a directory of federally and privately supported research trials conducted in the United States and around the world to test the effect of experimental drugs, devices, and procedures for many diseases and conditions.

Each entry includes a summary of the trial protocol, including the purpose, recruitment status, and criteria for patient participation. Trial locations and specific contact information are provided to assist enrollment.

The Web site is a free service of the U.S. National Institutes of Health (NIH), developed by the National Library of Medicine.

Linking Patients to Medical Research

Why register?

- **Required by law.** Section 113 of the FDA Modernization Act mandates registration with ClinicalTrials.gov of investigational new drug (IND) efficacy trials for serious diseases or conditions.
- **Required for journal publication.** The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for publication of research results generated by a clinical trial (*N Engl J Med* 2004;351:1250–1).
- **NIH commitment.** The NIH is committed to providing information to increase public awareness and access to clinical trials sponsored federally and by industry and foundations.

Which of my trials should be registered?

- ClinicalTrials.gov accepts registration of all clinical trials (1) approved by a human subject review board and (2) conforming to the regulations of the appropriate national health authorities. Both interventional and observational trials are accepted.
- Sponsors, funders, reviewers, ethics board members, and coordinators and investigators of clinical research anywhere in the world should be familiar with ClinicalTrials.gov registration policies.
- Trials can be registered at any time, but many policies require registration prior to the enrollment of the first participant.

Information about these policies and background materials are available at http://prsinfo.ClinicalTrials.gov.