How do I register my trial and report results?

- **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.
- **View the "Quick Start Guide."** All the features required to enter data about a trial are available through the "Standard Functions" menu.
- **Complete the 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 it is released 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.
- **Adding results,** once your record has an NCT number, you will be able to modify it and add results.

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 and Reporting Results of Clinical Trials
http://prsinfo.ClinicalTrials.gov

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

The International Committee of Medical Journal Editors (ICMJE)
http://www.icmje.org

FDAAA Certification to Accompany Drug, Biological Product, and Device Applications or Submissions
See http://www.fda.gov and search on keywords "FDAAA certification"

Registering & Reporting Results

with ClinicalTrials.gov

Linking Patients to Medical Research

prsinfo.ClinicalTrials.gov

What is ClinicalTrials.gov?

ClinicalTrials.gov is a registry of federally and privately supported research studies conducted in the United States and around the world.

Each entry is provided by the sponsor and 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. Some entries provide summary study results, including number of participants starting and completing the trial, baseline characteristics, outcome measures, and adverse events information.

ClinicalTrials.gov 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 801 of the Food and Drug Administration (FDA) Amendments Act mandates the registration with ClinicalTrials.gov of certain clinical trials of drugs (including biological products) and medical devices subject to FDA regulations for any disease or condition. For details, see http://prsinfo.ClinicalTrials.gov.
- **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. http://www.icmje.org

Which of my trials can 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 studies 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 and relevant local laws and policies related to registration.
- 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.