ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov Background

Contents

What is ClinicalTrials.gov?

ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study. In some cases, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry" and "results database."

ClinicalTrials.gov contains information about medical studies in human volunteers. Most of the records in ClinicalTrials.gov describe clinical trials (also called interventional studies). A clinical trial is a research study in which human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects on biomedical or health outcomes. ClinicalTrials.gov also includes records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access). Studies listed in the database are conducted in all 50 States and in 190 countries. ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered. However, the number of studies registered each year has increased over time as more policies and laws requiring registration have been enacted and as more sponsors and investigators have voluntarily registered their studies.

ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA required the U.S. Department of Health and Human Services, through NIH, to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug (IND) applications to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions. NIH and the Food and Drug Administration (FDA) worked together to develop the site, which was made available to the public in February 2000.

The ClinicalTrials.gov registration requirements were expanded after Congress passed the FDA Amendments Act of 2007 (FDAAA). Section 801 of FDAAA (FDAAA 801) requires more types of trials to be registered and additional trial registration information to be submitted. The law also requires the submission of results for certain trials. This led to the development of the ClinicalTrials.gov results database, which contains information on study participants and a summary of study outcomes, including adverse events. The results database was made available to the public in September 2008. FDAAA 801 also established penalties for failing to register or submit the results of trials. See the History, Policies, and Laws page for more information about the development of ClinicalTrials.gov.

Because ClinicalTrials.gov is a government Web site, it does not host or receive funding from advertising or the display of commercial content.

TO TOP

What Information Can I Find on ClinicalTrials.gov?

Each ClinicalTrials.gov record presents summary information about a study protocol and includes the following:

- Disease or condition
- Intervention (for example, the medical product, behavior, or procedure being studied)
- Title, description, and design of the study
- Requirements for participation (eligibility criteria)
- Locations where the study is being conducted
- Contact information for the study locations
- Links to relevant information on other health Web sites, such as NLM's MedlinePlus® for patient health information and PubMed® for citations and abstracts for scholarly articles in the field of medicine.

Some records also include information on the results of the study, such as:

- Summary of adverse events experienced by study participants

The full history of changes made to a record can be accessed by viewing the archival version of the record on the ClinicalTrials.gov archive. Once a study is registered on the site, the information about it is not removed.

TO TOP

What Can I Do on This Site?

- **Find and view clinical studies.** Conduct basic and advanced searches of clinical study records; browse studies; and search studies by topic, country, or region. See the Find Studies section of the site.
- **Learn more about clinical research.** Find out how clinical studies are conducted and who can participate. See Learn About Clinical Studies.
- **Manage study records.** Find out how to submit and maintain study records, access the Protocol Registration and Results System, and enter summary information about study protocols and results. See the Submit Studies section of the site.
- **Use site tools and data.** View statistics on registered studies or download study records for analysis. See the Resources section of the site.

TO TOP

Additional Information

This site complies with the Health on the Net Foundation Code of Conduct (HONcode) standard for trustworthy health information. See the Certificate of Compliance.

This page last reviewed in September 2014