We're building a better ClinicalTrials.gov. Check it out and tell us what you think!

ABOUT SITE

What's New
ClinicalTrials.gov Background
About the Results Database
History, Policies, and Laws
ClinicalTrials.gov Modernization
Media/Press Resources

Linking to This Site
Terms and Conditions
Disclaimer

ClinicalTrials.gov Background

Contents

- What Is ClinicalTrials.gov?
- What Information Can I Find on ClinicalTrials.gov?
- What Can I Do on This Site?

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 on 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 contains records describing observational studies and programs providing access to investigational drugs

MPI EXHIBIT 1076 PAGE 1

DR. REDDY'S LABORATORIES, INC.
IPR2024-00009
Ex. 1076, p. 1 of 4

outside of clinical trials (expanded access). Studies listed in the database are conducted in all 50 States and in 221 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 (for example, observational studies and trials that do not study a drug, biologic, or device). See FDAAA 801 and the Final Rule for more information. However, the rate of study registration 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 (HHS), through NIH, to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug 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 summary information on study participants and 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. In September 2016, HHS issued the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) clarifying and expanding the registration and results information submission requirements of FDAAA 801. This regulation takes effect in January 2017.

An account of the development and expansion of ClinicalTrials.gov in response to changes in policies and laws is provided on the History, Policies, and Laws page.

Searching ClinicalTrials.gov does not require registration or personal identification. Because ClinicalTrials.gov is a Government Web site, it does not host or receive funding or advertising from commercial entities or display 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 of scholarly articles in the field of medicine

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

- Description of study participants (the number of participants starting and completing the study and their demographic data)
- Outcomes of the study
- Summary of adverse events experienced by study participants

ClinicalTrials.gov was made available to the public on February 29, 2000, and the results database was released in September 2008. Once a study is registered on the site, it is not removed. The full history of the changes made to a record can be accessed by clicking on the **History of Changes** link near the bottom of the full text view of each record.

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 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.

MPI EXHIBIT 1076 PAGE 3

DR. REDDY'S LABORATORIES, INC.
IPR2024-00009
Ex. 1076, p. 3 of 4

- **Use site tools and data.** View statistics on registered studies or download study records for analysis. See the Resources section of the site.

This page last reviewed in May 2021

TO TOP

MPI EXHIBIT 1076 PAGE 4

DR. REDDY'S LABORATORIES, INC.
IPR2024-00009
Ex. 1076, p. 4 of 4