About ClinicalTrials.gov

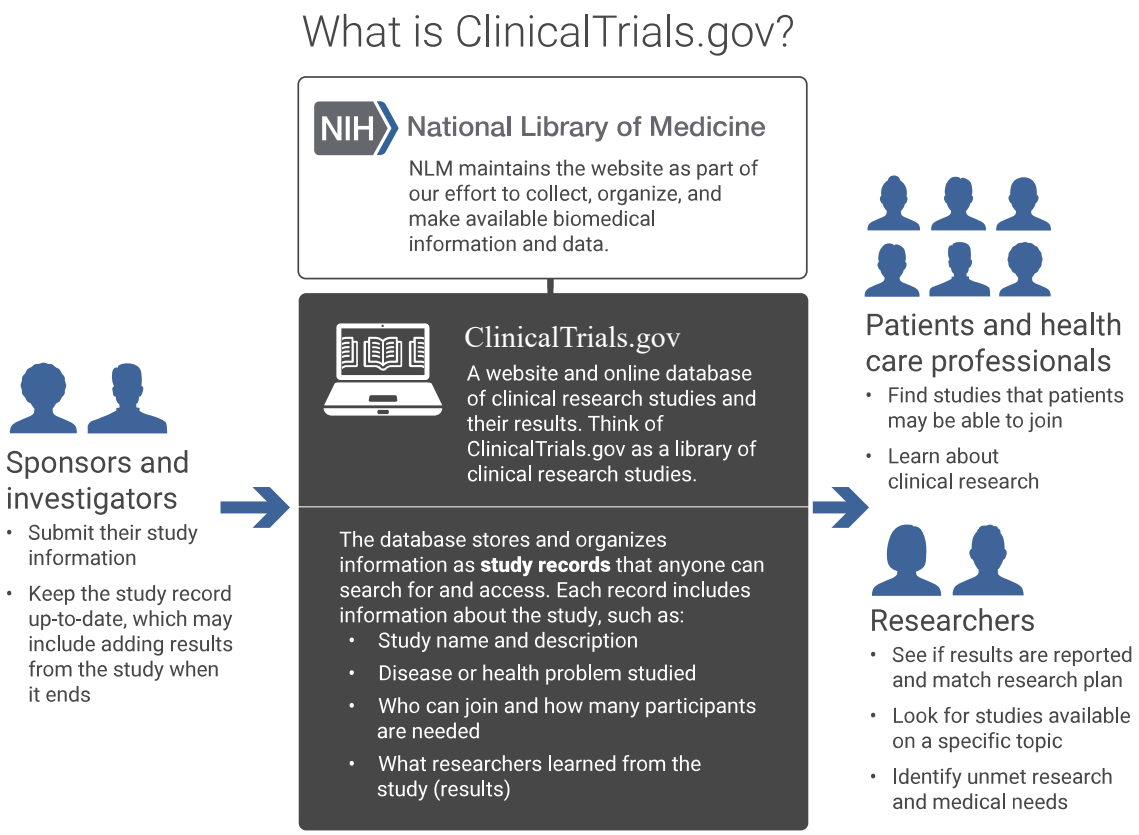
What is ClinicalTrials.gov and who uses it?

ClinicalTrials.gov is a **website** and **online database** of clinical research studies and information about their results. The purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals. The U.S. government does not review or approve the safety and science of all studies listed on this website.

ClinicalTrials.gov:

- Relies on sponsors or investigators to submit and update information about studies
- Lists up-to-date information on clinical research studies and their results with new studies added almost every day
- Includes studies that take place in all 50 states and over 200 countries
- Supports laws, regulations, and policies that require sponsors and investigators to publicly share information about clinical trials, including results

JHU 2145
Merck Sharp v. Johns Hopkins
IPR2024-00623



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Does the U.S. Government approve all studies listed in the ClinicalTrials.gov database?

No. The U.S. government does not review or approve the safety and science of all studies listed in the ClinicalTrials.gov database. The National Institutes of Health (NIH) and other U.S. agencies only approve the studies that they fund. U.S. government agencies do not fund all the studies listed on ClinicalTrials.gov.

The National Library of Medicine (NLM) does a limited review of the study information that sponsors and investigators submit to be included in the study record in the ClinicalTrials.gov database. The study sponsor or investigator is responsible for the safety, science and accuracy of any study they list on ClinicalTrials.gov. They are also responsible for ensuring that their study follows all relevant laws and regulations.

What clinical studies can be listed in the ClinicalTrials.gov database?

ClinicalTrials.gov lists studies that involve people, have health-related research questions, and follow ethics review and other health authority rules and laws.

The ClinicalTrials.gov database includes these types of studies:

- **Clinical trials**: research studies in which researchers assign participants to get one or more interventions (such as a drug, behavior, or medical device) to test what happens in people.
- **Observational studies**: research studies in which researchers simply collect information (called data) from participants or look at data that was already collected. The data may be about participants' health, habits, or environments. In observational studies, researchers **do not** assign participants to get an intervention. If there is an intervention, participants were already using it as part of their regular health care or daily life.

Learn more about types of clinical research studies on the Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies) page.

Expanded access

ClinicalTrials.gov also lists expanded access. **Expanded access** is a possible way for a patient with a serious illness who is unable to take part in a clinical trial to get an intervention (such as a drug or medical device) that isn't approved for treatment. Expanded access is not available for all interventions being tested. The study record includes who to contact to learn more. Read more about expanded access on the FDA's website (https://www.fda.gov/news-events/public-health-focus/expanded-access).

Is every research study listed in the ClinicalTrials.gov database?

No. Sponsors and investigators list studies in the ClinicalTrials.gov database based on laws and policies or by choice. Laws and policies around the world have set the expectation that clinical trials be listed on public databases, such as ClinicalTrials.gov. The U.S. has laws, regulations and policies requiring sponsors and investigators to submit certain types of clinical trials to ClinicalTrials.gov. Few policies require sponsors and investigators to list observational studies on public databases.

For research studies that aren't required to be submitted by law or policy, sponsors and investigators can choose to submit to ClinicalTrials.gov or not. If they choose to list the study on ClinicalTrials.gov, they must keep the study record up-to-date.

Learn more about the rules and laws for submitting studies on the Clinical Trial Reporting Requirements (https://clinicaltrials.gov/policy/reporting-requirements) page.

Who submits information about a clinical study to the ClinicalTrials.gov database?

Study sponsors and investigators submit the information to ClinicalTrials.gov. Sponsors and investigators are responsible for ensuring that their studies follow all relevant laws, regulations, and policies.

What information about clinical studies can be found in the ClinicalTrials.gov database?

The ClinicalTrials.gov database includes information about clinical research studies that are happening now, will happen soon, or happened in the past. Information about each study is permanently available in the database, even after the study ends.

Information submitted about the study can be viewed in one place, called the study record. Each version of the study record is also permanently available. A study record includes:

General information about the study:

- Study name and description
- Person or organization responsible for the study (sponsor or investigator)
- People or organizations that fund or provide support for the study
- Disease or health problem studied
- Start and end dates
- Locations

Specific information about the study:

- Who can and cannot join (eligibility criteria)
- How many study participants are needed
- A description of the intervention(s) that may be given (such as a drug, medical device, or behavior)
- What researchers want to learn and how they will measure it

- How to contact the study staff

Some, but not all, study records contain more information, such as:

- The study protocol, analysis plan, and informed consent form
- What researchers learned from the study (results)

Does ClinicalTrials.gov include information about study results?

Yes, the Results tab of a study record may include study results for certain clinical trials. The study sponsor or investigators may submit study results, usually no later than 1 year after a study is completed. When results are available for a study, the Results tab is labeled "Results Posted." For help finding results in a study record, see How to Read Study Results (https://clinicaltrials.gov/study-basics/how-to-read-study-results).

Study results are in a table format and include:

- A description of the groups of participants who joined the study and their traits, like their average age – it doesn't include any information that could identify an individual participant (or any individual participant data)
- Findings from the study
- A summary of any health problems (adverse events) that happened during the study

Study results do not include any conclusions or interpretations of the results. For more information, see How to read each section of the study results (https://clinicaltrials.gov/study-basics/how-to-read-study-results#results-sections).

ClinicalTrials.gov staff review study results to make sure they are clear and informative before being posted. ClinicalTrials.gov staff do **not** review for scientific accuracy. The study sponsor or investigators are responsible for making sure the results are accurate and complete before they submit them.

The study sponsor or investigators can also submit links to publications (papers in scientific journals) related to the study results. The Publications section under the Results tab will include these links, if provided. ClinicalTrials.gov staff does not review or oversee the publications.

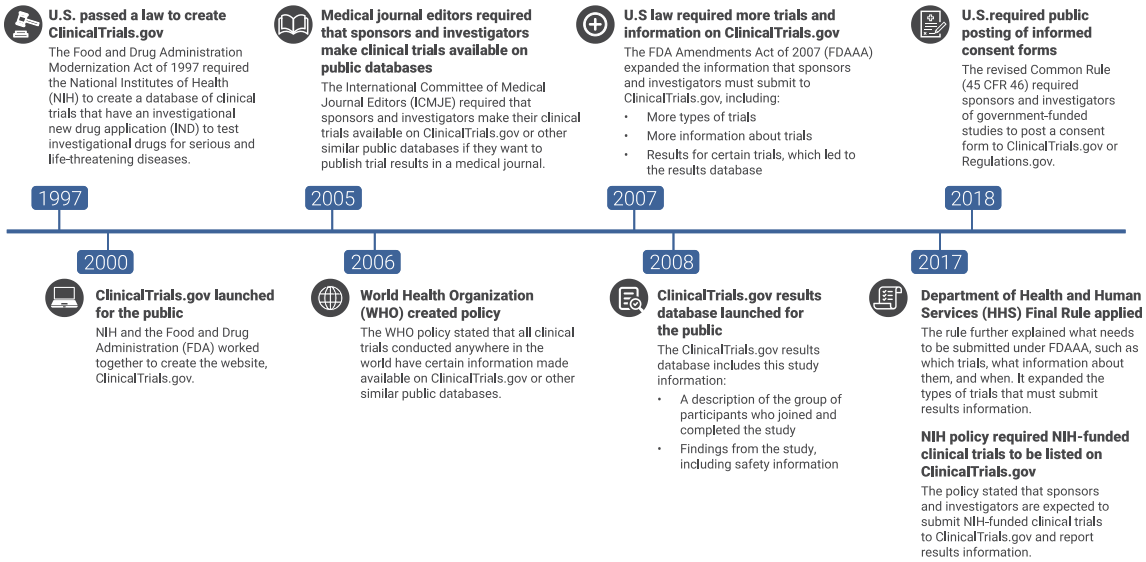
Why was ClinicalTrials.gov created?

ClinicalTrials.gov launched in 2000 and was created as part of a law that was passed in 1997 (Food and Drug Administration Modernization Act of 1997). This law required the U.S. National Institutes of Health (NIH) to create a database of clinical trials that have an investigational new drug (IND) application (https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application) to test investigational drugs for serious or life-threatening diseases.

Since then, ClinicalTrials.gov has expanded based on other laws, regulations, and policies to include more types of research studies and more information about these studies. These laws, regulations, and policies ensure that information about ongoing and completed studies and their results are publicly available for people to consider joining and to inform future research.

The image below shows major events related to ClinicalTrials.gov and how the study information listed in the database has changed over time:

Major milestones related to ClinicalTrials.gov and how information in the database has changed over time



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Read more about the Clinical Trial Reporting Requirements (https://clinicaltrials.gov/policy/reporting-requirements) of ClinicalTrials.gov.

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