ClinicalTrials.gov

National Library of Medicine

How to Read a Study Record

Learn how to read and understand a study record on ClinicalTrials.gov (https://clinicaltrials.gov/).

Quick Guide to Finding Information
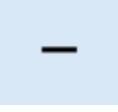
The study record includes these main parts:

- Study introduction area – Found at the top of the page when you first open a study record. Information found here:
    - The study title – describes what the study is about
    - Study status – tells if this study is accepting participants, is completed, or has results
    - Other administrative information – study identification numbers, the study sponsor, the responsible party who entered the information, and the date the study was last updated.

- Study details – This is the tab already open below the introduction. It contains important study details organized into sections by the type of information. Some of the information found here:
    - Study contacts and locations – who to call with questions and where the study is taking place
    - Eligibility (Participation Criteria) – the criteria for participating in the study
    - Study design – describes how the study will work
    - Other people involved with the study

- Researcher View – Provides information of interest to data researchers and journal editors organized in a way that works best for them

- Results – The study results will be found here if they are available.
    - "Results Posted" means the study results are available.
    - "No Results Posted" means the study results are not available.
    - "Results Submitted" means the study results are under review before being posted.

- Record History – A table that documents changes to the study record over time. Each version is listed according to the date the version was posted.

On a desktop or laptop computer, several of the tabs include a left-sided menu that allows users to navigate to a specific section.

Feedback

As you scroll through a study record on a mobile device, the title of the next section will appear at the bottom on the screen. As you move down the record, the title of the previous section will appear at the top of the screen.

Helpful features:

Feature	Function
i	Click on this to see the glossary definition for the term
+	Click on this to see more information in part of the study record
—	Click on this to close part of the study record
Expand all content **Collapse all content**	Click on Expand all content to view all information in the study record Click on Collapse all content to view less information in the study record
+ Show more	Click on this to view more information
— Show less	Click on this to view less information

Finding Information in the Study Record

The Study Introduction area

In this area you'll find information important to the entire study record:

- Study status – whether the study is currently looking for participants, is completed, or has results
- Brief title of the study – a short title that describes what the study is about
- ClinicalTrials.gov ID (NCT number) – the ID number assigned to this study when it was registered on ClinicalTrials.gov

- Study sponsor – the organization or person who has control over the study
- Information provided by – the person or organization responsible for entering the study information, also called the Responsible Party
- Last update posted – the last time changes were made to the study record

The Study Details tab

The Study Details tab is the default view. It opens when you first look at a study record. This tab contains information about the people involved in the study, how it will be conducted, and information about participation.

There are 8 parts:

- Study Overview
- Contacts and Locations
- Participation Criteria
- Study Plan
- Collaborators and Investigators
- Publications
- Study Record Dates
- More Information

To jump to a section, click on the title in the menu to the left.

Study Overview

This section tells you what the study is about, how it will work, the dates that study will likely start and stop, and the number of participants.

On the left side of this section, you'll find:

- **Brief Summary and Detailed Description:** Tells you the purpose of the study and how it will work.
- **Official Title:** The title given to the study by the researchers, often written in scientific language.
- **Conditions:** The focus of the study, usually a disease, illness, or condition, but may also be another health-related issue.
- **Intervention/Treatment:** The treatment, device, or procedure that's being studied.

On the right side of this section, you'll find:

- **Study Dates:** The study start dates and completion dates. Some of these may be estimated dates.

- **Enrollment:** The number of participants who joined a study or who the researchers hope will join the study.
- **Study Type** – A study may be one of three basic types:
  - Interventional (also called clinical trials) – Participants are assigned to receive an intervention so that researchers can study the effects.
  - Observational (including patient registries) – Participants do not receive an assigned intervention. They are observed over time for health-related outcomes.
  - Expanded access – A way for patients with serious conditions to receive a drug or treatment outside of a clinical trial.

    Note: The study records for each type of study will have different types of information available.
- **Phase:** The stage of the study, based on definitions from the U.S. FDA.
- **Other Study ID Numbers:** other identifying numbers for the study
- **Expanded Access:** This will appear if expanded access is available.

At the bottom of the Study Overview, the National Library of Medicine provides resource links to learn more about topics related to the study.

Contacts and Locations

This section provides information on who to contact for questions about the study and where the study is taking place.

- **Study Contact:** The name and contact information for someone who can answer questions about the study.
- **Study Contact Backup:** This may be available as an option if you can't reach the main study contact.

  Note: These fields are only available if the study status is "Not yet recruiting" or "Recruiting" and may not be available if there are individual contacts listed for each study location.
- **Study Locations and Map:** A map and list of locations in alphabetical order (by state then city within the United States) where the study is taking place. A location-specific study contact may be listed if the study status is "Not yet recruiting" or "Recruiting".

  Features of the map:

  - Red pins: Show specific study locations, also called clinical sites.
    - Click on a red pin to zoom to that location information in the list.
  - Blue circles: Show areas with many study locations.

- Click on a blue circle to zoom the map in to show red pins for each of the study locations in that area or more blue circles with more clusters of clinical sites.
  - If you click on a location in the list, the map will zoom in to show that location.
  - If you searched for a study using the location filter (entering an address or place), the map will already be zoomed in to that address or place, showing a circle representing the search distance and the study locations within it.
  - You can zoom in on the map by double clicking, or using your cursor. Hold down the 'Ctrl' button on your keyboard and use your mouse wheel to scroll up to zoom in and scroll down to zoom out.

Participation Criteria

This section gives details about the types of participants that the study researchers need for the study, also known as **eligibility criteria**.

Most records will show the participation criteria as:

- **Inclusion Criteria:** The characteristics of people who might be able to join the study.
- **Exclusion Criteria:** The characteristics of people who cannot join the study.

On the right side of the participation criteria:

- **Ages Eligible for Study:** The ages of people who can join the study.
- **Sexes Eligible for Study:** The biological sex of people who can join the study.
- **Accepts Healthy Volunteers:** This tells if the study accepts participants who are healthy.

Study Plan

This gives details about how the study is set up and what the study is measuring. Click the + to view each of these sections:

- **How is the study designed?**
- **What is the study measuring?**

How is the study designed?

This section provides details on how the study will be run. This information may be different depending on the type of study.

- Interventional studies (clinical trials):
  - Design Details

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