CROHN'S & COLITIS FOUNDATION

CLINICAL TRIALS

FREQUENTLY ASKED QUESTIONS

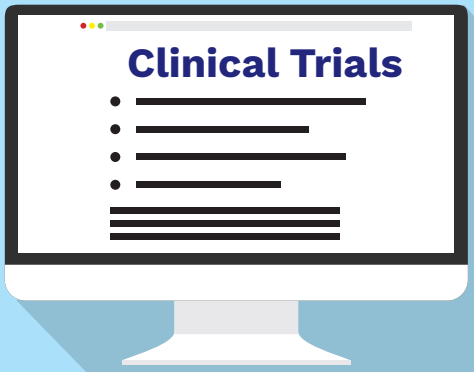
PARTICIPATING IN A CLINICAL TRIAL

What is a clinical trial?

Clinical trials are research studies that involve people. Through clinical trials, researchers find new ways to improve treatments and the quality of life for people with a specific disease. Clinical trials are one of the final stages of a long and careful research process, which often begins in a lab where scientists first develop and test new ideas.

How do I get involved in clinical trials?

Talk to your doctor about whether participating in a clinical trial may be right for you. Both you and your doctor can search all available clinical trials by visiting **trials.crohnscolitisfoundation.org**



How do I identify a clinical trial I am eligible for?

Each clinical trial has a set of guidelines for who can or cannot participate in the study. These guidelines, called **eligibility criteria**, describe characteristics that must be shared by all participants. The criteria differ from study to study. They may include age, gender, medical history, and current health status. If you are interested in a particular trial, be sure to read the eligibility criteria to see if you qualify.

What questions should I ask my doctor about getting involved in a clinical trial?

- Do you think a clinical trial may be right for me?
- Are there any trials I could enter with my Crohn's disease or ulcerative colitis?
- Do you know of any trials looking at new therapies or treatments?
- Can you tell me why this trial is being done?
- What are the possible advantages and risks of taking part in this trial?
- How many patients are in the trial?
- How long will the trial last?
- What will I have to do if I take part?

Are clinical trials free of cost to me?

The majority of clinical trials are federally or privately funded, so there is typically **no cost** to the participant.

Will my insurance cover the cost of a clinical trial or does the sponsor pay for my care?

Federal law requires most health insurance plans to cover the majority of routine patient care costs associated with clinical trials. However, **health plans are not required to cover all research costs.** Examples of these costs include extra blood tests or scans that are done purely for research purposes. However, the trial sponsor will often cover such costs.

What other costs may be associated with participating in a clinical trial?

Travel, gas, parking, and arranging for child care/time off work are other possible costs associated with participating in a trial. However, often times, the **trial sponsor** will cover these costs.

Can I drop out of the clinical trial if I need or want to?

Yes, absolutely. Research coordinators discuss this process at length during the consent process. If you drop out, the research coordinator will likely ask that you complete a **termination visit** and any safety follow-up visits to ensure you do not experience any side effects.

Do I need to live near a large hospital to take part in a clinical trial?

Not necessarily. Some clinical trials have participants who drive across the state to participate. There are also smaller offices who participate in clinical trials, but not as often. If necessary, some clinical trial sites will also help to **arrange transportation and hotel accommodations if needed**.

Can I be in a clinical trial for a new medication if I am currently on another IBD treatment?

Each clinical trial is very specific as to which medications you can currently be taking, as well as medications you have been on in the past. Prior to enrolling in a trial, a research coordinator will review your complete medication history to see if you meet the inclusion criteria. Some clinical trials may require a **"wash-out"** before you can start on the study drug, meaning the medication you are currently taking is fully out of your system.

Can I participate in a clinical trial if I'm currently in remission?

It depends on the study. Typically, clinical trials are for patients who have **moderate to severe disease**. A screening colonoscopy and biopsies are usually necessary to assess the severity of disease. Study sponsors assign scoring methods to determine the severity score of the patient's disease, and then monitor the score throughout the study, to see how well the study drug may be helping.

I cannot afford my current medication; can I access treatment through a clinical trial?

Depending on your eligibility, and whether or not your physician and the study team consider you a good candidate for a study, you may receive **study drug at no cost** as part of a clinical trial.

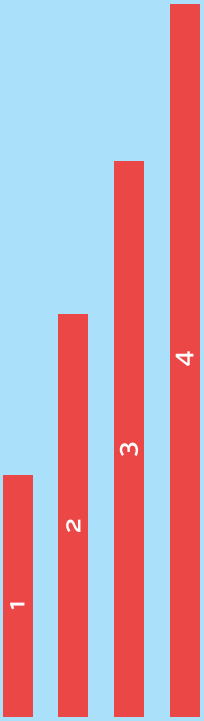
Does participating in a clinical trial take the place of my regular doctor appointments?

No. Trial participation **does not take the place of your regular doctor appointments**. Standard prescriptions, surveillance tests, and procedures are still needed, so patients should maintain their care with their physicians and keep them informed regarding their study participation.

ABOUT CLINICAL TRIALS

What is a clinical trial protocol?

A clinical trial protocol is a document that describes **how a clinical trial will be conducted** (objectives, study design, methodology, organization of a clinical trial) and also ensures the safety of all trial participants and the integrity of the data being collected.



What is a trial phase?

Clinical trials are conducted in a series of steps, called **phases**. Each phase is designed to answer a separate research question.

- **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

What does “standard of care” mean?

Standard of care is a treatment that is accepted by medical experts as a proper treatment for a certain type of disease that is **widely used by healthcare professionals**. Standard of care is also commonly referred to as best practice, standard medical care, and standard therapy.

What does an investigational treatment or procedure mean?

An investigational drug is one that is currently under clinical study but **does not have permission** from the U.S. Food and Drug Administration (FDA) to be legally marketed and sold in the United States. FDA approval is the final step in the process of drug development.

What is a control or control group?

The control group is defined as the group in an experiment or trial that **does not receive treatment**. The control group is then compared to the group receiving the study treatment to see if the treatment is working.

What is a randomized clinical trial?

A randomized clinical trial is a study in which people are **chosen at random** to receive the treatment being studied.

Why are patients randomized?

Randomization in clinical trials uses chance alone to assign participants to a study group, meaning that each group will be **similar in demographics**. The purpose of randomization is to ensure that the new treatment being tested against a placebo or existing treatment is being compared and measured fairly.

What is a blinded trial?

Blinding a clinical trial is a design strategy in which one or more parties involved in the trial, such as the investigator (the individual who is responsible and accountable for conducting the clinical trial) or participants, do not know which participants have been assigned which treatments. This also helps to ensure that the treatments being tested are **compared fairly**.

What is a placebo?

A placebo is a pill or liquid which often looks like the real medical treatment being studied in a clinical trial, except it **does not contain the active medication**.

What happens if I receive the placebo?

This is a question that we hear a lot. Typically, participants are not told what treatment they are being given until a clinical trial is over. So, **participants will not know** if they are receiving the study drug or placebo during the trial. Research coordinators and trial staff themselves often do not know which participants are receiving the study drug or placebo. This helps reduce possible biases and ensures the fairness of the trial.

All participants, whether on a placebo or the treatment, are **monitored very closely** during the clinical trial. If there is any change in your medical condition while participating in the study, the research staff will inform you immediately and discuss the situation. For example, if you are a participant that receives a placebo and your condition does not improve or your symptoms worsen, the research staff can recommend that you stop the trial or that you talk with your doctor about receiving another medical treatment. Whichever group you are in, you can expect to receive excellent medical care during the trial.

What is the average length of a clinical trial?

The length of a clinical trial varies. Some trials can be 4-12 weeks in length, while others can last from 24-52 weeks or even longer.

What is informed consent?

Informed consent is when participants give their permission to participate in a trial with the **knowledge of possible consequences** and an understanding of the possible risks and benefits.

If I enroll in a clinical trial, can I ask about the results of the study to date; e.g. results from earlier phases of the trial?

Yes. Information that has been obtained from **earlier completed clinical trials** should be made available to you. The data from previous trials are used to inform the design of the current clinical trial.

Can I ask about the side effects the research staff have observed in other patients?

No. Because of privacy rights, research staff cannot discuss other patients' medical histories. They can, however, tell you about side effects that have been **identified in previous trials**.

What happens when the trial is over?

When the trial is over, the database is closed and the **information is analyzed** to determine the effectiveness of the new treatment being studied. You will eventually be told if you received the active drug or a placebo. This can, however, take some time to be reported back to you.

What happens if I am doing well on the new drug or therapy? Can I keep using it while the sponsor seeks FDA approval?

This depends on the sponsor of the study. Some sponsors will allow patients to continue to receive the drug. However, others may not have access to the new treatment until it is formally approved by the FDA.

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