

A full-page background image with a blue tint. It shows a close-up of a person's face, wearing safety goggles and a lab coat, looking through the eyepiece of a microscope. The person's hand is visible, adjusting the microscope's stage. The text is overlaid on this image.

YOUR GUIDE IN THE FIGHT

Clinical Trials

A **FIGHT COLORECTAL CANCER™** Resource

Who Are *Clinical Trials* for?

Clinical trials are done for many diseases – including colorectal cancer – and within different groups of people (age, ethnicity, sex).

Some need healthy volunteers, while other clinical trials seek participants needing treatment. Researchers may be recruiting patients of a certain age, with a tumor in a specific location, or patients who have a certain genetic mutation or biomarker. Other clinical trials may address side effects or quality of life issues, such as neuropathy or skin toxicity.

Sometimes when people think of clinical trials, they think, “last ditch efforts.” This is a myth. Clinical trials are for anyone at any time who meet the trial’s eligibility requirements.

The best time to investigate clinical trials is when you and your medical team are embarking on a new therapy and want to examine possible treatment options. Also, keep in mind that new clinical trials are always opening and recruiting, so what may be available one day, may not be available the next.

There are also timelines to take into consideration when reading clinical trials criteria, such as the length of the trial, and frequency and length of required clinical visits while the trial is ongoing. Although searching and applying for clinical trials may feel daunting, a clinical trial may be worth your time and effort.

A clinical trial’s protocol describes:

- * Specifics of volunteers that may enter the study
- * Length of the study
- * The schedules of tests and procedures, medications, and dosages
- * Number of study visits

Based on the requirements of the protocol, you may or may not qualify for a specific clinical trial. Just because you do not qualify for one trial does not mean that you will not qualify for another. If you do not meet the specific parameters that a clinical trial is testing for, there are many trials out there, so keep looking!

Participation is always voluntary, and you can withdraw from the trial at any time.

Like all treatment options, there are potential benefits and risks to consider. If you are considering a clinical trial, ask your healthcare team as many questions as you need to.

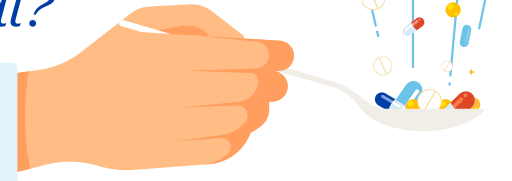
POTENTIAL BENEFITS

- * You may have access to a new treatment that is not otherwise available.
- * Your health will be closely monitored by the research team.
- * If the treatment being studied is more effective than the standard treatment, you may be one of the first to receive and benefit from it.
- * Even if you don’t directly benefit, information learned from the trial can help other patients and increase knowledge about colorectal cancer.

POTENTIAL RISKS

- * New treatments aren’t always better than the standard treatment available. In some situations, they may be less effective.
- * There may be unexpected side effects or side effects that are worse than the standard treatment.
- * You may have more doctor’s visits than if you were receiving the standard treatment.
- * You may need extra tests, which can be time-consuming or uncomfortable.

Will I Receive a Placebo During a Trial?



Clinical trials often compare a drug within study groups. If a clinical trial involves placebos, it is important to note that the participants in the clinical trial continue to receive the standard of care treatment. In cases in which there is no known effective treatment option or standard of care, then a placebo may be used in a clinical trial. Trial participants will always be informed that they may receive a placebo in these situations.

In other words, at the minimum, participants receive all treatments they would receive if not in a clinical trial. Placebos are not used in clinical trials where volunteers will be harmed if they do not receive a real medical treatment for their condition.

The point of clinical trials is to evaluate the safety and effectiveness of treatments or devices; they aim to improve the health and quality of life of those participating.

What if the Clinical Trial Doesn’t Work?

If researchers and doctors find that the experimental treatment is not working or is harming participants, they will stop the trial immediately. Safety of participants is the top priority.

Who Pays for Clinical Trials?

Patients don’t usually have to pay to participate in a clinical trial because the trial will pay for any special testing or research-related fees, **but there are costs that patients may still be responsible for.**

Copays and coinsurance: Routine care that would be considered a part of your “standard treatment plan” may be covered by your insurance plan, but you would be responsible for your standard copays or coinsurance. Some trials may choose to cover your portion of these costs.

Travel and meals: Some trials will offer reimbursement for travel costs and meals if you have to travel to participate, however not all do. Be sure to ask if this is not explained during informed consent.

Other costs: There are other costs to consider when you participate in a clinical trial. How much is parking, gas, and tolls? Will you have lost income from having to take extra time off of work for extra visits to the hospital/medical center? What are the costs to your caregiver if they are going to appointments with you (you may not be able to drive with some trials)?

Paid participation: There are clinical trials that will pay you for your participation. This may offset some of your out-of-pocket costs, but make sure you talk to your medical team about potential trials that are best for you.

What Is a Clinical Trial?

You have a backache after a day of yard work — what do you do? Pop an ibuprofen and wait a few minutes. Flu season hits, and you want to avoid it. You go get a flu shot.

From over-the-counter drugs to prescription drugs and vaccines, all of our modern medicines have been thoroughly investigated and researched. The Food and Drug Administration (FDA) is the regulatory organization that ensures medications in the U.S. are safe and effective for consumer use. **How do they know what's safe? They learn through clinical trials.**

Types of Clinical Trials

There are lots of different kinds of trials that need participants every day.

Clinical trials test new ways to:

- * Prevent colorectal cancer
- * Find and diagnose colorectal cancer more effectively or earlier
- * Treat colorectal cancer
- * Manage symptoms or side effects of colorectal cancer






If you're interested in advancing science and getting involved, there's probably a trial available to you. The good news? Your participation is what advances research and makes scientific breakthroughs. Without you, we would not make progress in the fight against colorectal cancer.

How Do Clinical Trials Work?

Before new treatment can even reach patients enrolled in clinical trials, they go through a rigorous pre-clinical research phase. During this phase, the drug or treatment is studied in laboratory animals for safety and efficacy.

The goal of clinical trials for treatment is to make cancer treatment individualized, with fewer side effects, so people can live longer with a better quality of life, and ultimately to find cures.

Researchers and doctors follow strict guidelines to protect trial participants while collecting information to assess medical protocols, treatments, medical devices, and more. They do this to learn if these clinical trial drugs work and if they are safe.

Pre-Clinical	Phase 1	Phase 2	Phase 3	Phase 4
				
Animal studies.	This phase focuses on the safety and proper dose.	This phase focuses on effectiveness and side effects.	This phase compares the new treatment to existing treatment.	Now, treatment is approved and available . Long-term side effects are observed.
● Takes about 6 years	● Takes about 1 year	● Takes about 2 years	● Takes about 2 years	● Takes about 5+ years
Average Number of Trial Participants: 5-50 people		Less than 100 people	Hundreds of people	Thousands of people

Terms TO KNOW /

Control Group: The group in a clinical trial that does not receive the new treatment being studied. The control group is compared with the group that receives the new treatment to see if the new treatment works.

Double Blind Study: A type of clinical trial in which neither the participants nor the researcher knows which treatment the participants are receiving until the clinical trial is over. This helps to prevent bias when interpreting the results of the trial. Not every trial is well-suited to be performed as double blind.

Protocol: A detailed plan that describes the steps of a clinical trial or treatment. The protocol outlines how the clinical trial will be carried out. Based on the requirements of the protocol, you may or may not qualify for a specific clinical trial. If you qualify for the clinical trial, you will be asked to agree in writing to follow the protocol. This is called "giving informed consent."

Informed Consent: The process in which a person is informed of the purpose, methods, and risks of a procedure, and then agrees to receive treatment. The informed consent outlines what you are committing to. Even if you sign it, you have the right to change your mind later, because you are always in control of your health care. You can withdraw from the clinical trial at any time.

Standard of Care (SOC) or Standard Treatment: Also called "best practice." This is a leading treatment used by medical professionals to treat a certain disease. This is the treatment you would receive if you don't participate in a clinical trial. Standard of care often differs depending on the patient's unique situation.

FIND US ONLINE!

Join our online community of survivors and patients searching for clinical trials to ask peer-to-peer questions and find help!



SCAN HERE
to learn more

Join us at
[Community.FightCRC.org](https://www.Community.FightCRC.org)



Questions to Ask Your Healthcare Team

1. Am I eligible for a clinical trial? If yes, do you feel that would be a good choice for me?
2. What are my treatment options?
3. What is the standard treatment for someone in my situation?
4. What do you recommend?

Questions About Risks and Benefits of the Clinical Trial

1. Why do you think a clinical trial might work for me?
2. What are the possible side effects or risks? What are the possible benefits?
3. How do the possible risks and benefits of this trial compare with my other treatment options?

Questions About Your Rights

1. How will my health information be kept private?
2. What happens if I decide to leave the trial?

Questions About Costs

1. What costs will my health insurance cover? Will I have to pay for any part of the clinical trial?
2. Will I be reimbursed for costs of travel, parking, or meals incurred while I am participating in a clinical trial?
3. Who can I talk with about costs and payments?

Questions About Daily Life

1. How could the trial affect my daily life?
2. How often will I have to come to the hospital or clinic?
3. Will I have to stay in the hospital during the clinical trial? If so, how often and for how long?
4. How far will I need to travel to take part in the trial?
5. Will I have checkups after the trial?

How Do I Find a Clinical Trial?

Fight CRC Clinical Trial Finder: A one-stop place to find and learn more about high-impact clinical trials for colorectal cancer patients. The list of trials curated here is sourced daily from the ClinicalTrials.gov website by trained research advocates and can be accessed at [TrialFinder.FightCRC.org](https://trialfinder.fightcroc.org).

The trial listings are curated using a process grounded in the patient perspective, emphasizing the relationship between patient values and the desire to find clinical trials with a meaningful impact on their treatment.



SCAN HERE
to learn more

Search at
[TrialFinder.FightCRC.org](https://trialfinder.fightcroc.org)



MAIA WALKER

Lead Trial Finder Curator

"The Fight CRC Trial Finder is a great place for patients and caregivers to come and find trials that have been curated by patient advocates, who know how it feels when lives are on the line."

ClinicalTrials.gov: A database of publicly and privately funded clinical trials conducted around the world.

Your Doctor or Healthcare Team: Ask your doctor or healthcare team if they know of clinical trials that you might consider. They may be able to help navigate you to the clinical trial that's right for you.

Blogs and Advocacy Forums: Online searches can yield helpful posts with summaries of clinical trials explained in an approachable way that patients can understand. Fight CRC's monthly Clinical Trial Conversations blog posts do exactly this.

***Be sure to discuss any potential clinical trials you find with your medical team.**

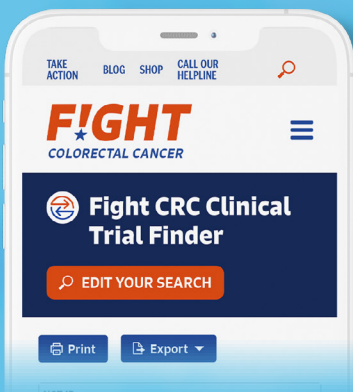
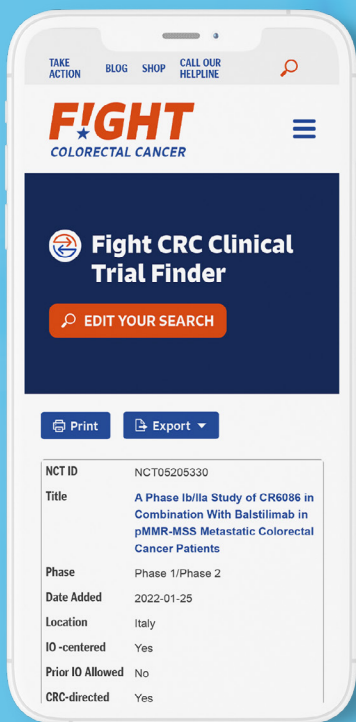
Representation Matters

People who are underrepresented in health care are generally likely to also be underrepresented in clinical research. For many years, clinical trials were done on white men only.

Today, clinical trials welcome the participation of all people who meet the trial's eligibility, and these clinical trials are closely monitored to ensure safety and ethical treatment of all patients who participate.

Because patients may experience the same disease differently, it is extremely important to include people with a variety of lived experiences and backgrounds, as well as differing characteristics like race, ethnicity, and age, so that all communities benefit from scientific advances in clinical trials.





LOOKING FOR α *Clinical Trial?*

Fight CRC has made it easy to find clinical trials that are relevant to the colorectal cancer community. The list of trials curated here is sourced daily from the ClinicalTrials.gov website by trained research advocates and can be accessed at ***TrialFinder.FightCRC.org***.

The trial listings are curated using a process grounded in the patient perspective, emphasizing the relationship between patient values and the desire to find clinical trials with a meaningful impact on their treatment.



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All medically-reviewed content was written by Fight Colorectal Cancer.
This educational resource was made possible thanks to the following support:

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