COLORECTAL CANCER

Clinical Trials

A Guide to Understanding Your Role in Cutting-Edge Research

FIGHT COLORECTAL CANCER

What is a Clinical Trial?

Clinical trials explore new ways to prevent cancer, diagnose it earlier, treat it more effectively, and manage side effects. Every medicine and many tests used today were once studied in trials.

> **MYTH** Trials are only a "last resort".
>
> **FACT** You can ask about trials at diagnosis and at every treatment decision point.

WHO ARE TRIALS FOR—AND WHAT TO EXPECT

Trials are designed for people who match clear criteria (your cancer type/stage, biomarkers, your prior treatments, and general health). There are trials for those newly diagnosed, for people whose cancer has grown or returned, and for managing side effects and day-to-day quality of life.

Joining a trial can be time-consuming, but worthwhile. Participating in a trial usually involves pre-screening, sharing your medical records and biomarker report, possible baseline tests, and insurance and logistics checks. Sites may have limited openings or specific timing windows.

Don't be discouraged. Ask your team to pre-screen early, keep standard care moving while you explore options, and revisit trials at each treatment decision.

3 Questions to Ask

1. Am I eligible for any clinical trials now?
2. How do the risks and benefits compare with my other options?
3. If this trial isn't right for me, what's next or when should we revisit trials?

> *"I kept checking trials with my oncologist. When chemo failed me again, we found a trial at my center that fit. I stayed on it for well over a year —much-needed time off chemo without being off treatment."*
>
> Phuong G.
> STAGE IV SURVIVOR
>
> ***Ready to tell your story and offer advice? fightcrc.org/story***

Sign up for our Clinical Trials Newsletter
fightcrc.org/trialnews

ADDITIONAL RESOURCES

ChatCRC Ask about clinical trial options using your biomarker report or text ChatCRC at (318) 242-8272. chatbot.fightcrc.org

Clinical Trials Roundup Visit our monthly Clinical Trials Roundup to view CRC specific trials at fightcrc.org/roundup.

A Resource for Patients by Patients

Terms to Know

STANDARD OF CARE (SOC) The proven treatment most people would receive for your situation outside a trial.

PROTOCOL The study's detailed written plan of what happens, when, who can join, required tests/visits, and safety monitoring.

CONTROL GROUP The comparison group (often standard of care) used to measure how well the study treatment works.

CROSSOVER ARM A trial design where participants may switch to the other treatment arm (for example, from control/SOC to the study drug) if predefined conditions in the protocol are met, such as cancer progression.

PLACEBO An inactive substance. In cancer treatment trials, a placebo alone is not used when an effective therapy exists; it's often used with standard of care (e.g., study drug + SOC vs placebo + SOC).

INFORMED CONSENT The process where the study is explained to you so you can make an informed decision on whether or not to participate. You can ask questions and withdraw your consent at any time during the trial.

How Do Trials Work?

PROTOCOL & CONSENT

Protocol Explains who can join, treatment and visits, tests/scans, duration, location/schedule, which costs are covered.

Informed Consent Explains your team reviews risks/benefits; you can ask questions and stop anytime.

COSTS

Most research-only costs will be paid by the study sponsor. However, you may still be responsible for some expenses, including:

- Routine care costs Copays/coinsurance for standard scans or labs
- Travel/parking/meals Some studies will reimburse these costs, be sure to ask
- Time costs Time off work, time spent traveling, childcare, caregiver time commitments

> **TIP** Ask whether the trial matches your biomarkers (e.g., MSI/MMR, RAS/RAF, HER2, NTRK), your prior lines of therapy, and your travel/time needs. Make sure to talk to your healthcare team to discuss the risks vs potential benefit of a clinical trial.

PHASE	FOCUS	# OF PARTICIPANTS	WHAT IT MEANS (CRC-SPECIFIC)
Phase 1	Treatment safety and proper dose	Dozens	First access to new drug/combo (often after standard options). Frequent early visits/scans; benefit uncertain; often biomarker-selected.
Phase 2	Does it help this cancer?	Dozens–hundreds	Looks for activity in CRC (e.g., MSI-H/dMMR, HER2+ mCRC). Single-arm or randomized (assignment by chance–like a coin flip–to keep results fair).
Phase 3	Comparing new treatment to existing treatment	Hundreds–thousands	Compare study + SOC vs placebo + SOC (or vs active control). You'll always get at least SOC; some trials may allow crossover if cancer continues to grow.
Phase 4	Monitoring after FDA approval	Hundreds–1,000s+	Real-world safety and effectiveness, as well as long-term side effects, are carefully observed for multiple years.

WILL I GET A PLACEBO?

In cancer treatment trials, a placebo alone is not used if an effective treatment exists.

You'll receive at least standard of care, or the placebo is used in addition to standard care (for example, study drug + SOC vs placebo + SOC). Placebo-only arms are used only when there's no proven effective therapy for that situation.

IMPORTANT

Safety oversight Trials are reviewed by an IRB (Institutional Review Board) and often monitored during the study by an independent DSMB (Data and Safety Monitoring Board) to protect participants. At a minimum, participants receive all treatments they would receive if not participating in a clinical trial.

Essentials for Searching for and Applying to Trials

- **Pathology and biomarker report** CRC examples: MMR/MSI, KRAS/NRAS, BRAF, HER2, NTRK
- **Cancer type and stage** Include sites of disease if metastatic
- **Prior treatments and side effects** Regimens, dates, best response, toxicities
- **Travel/time limits** Distance, schedule, caregiver needs
- **Top questions** Prioritize your 3 must-asks
- **Photo ID and insurance card** For site registration and billing
- **Medication and allergy list** For safety checks and drug interactions
- **Calendar or phone** To schedule visits and scans
- **Support person** For note-taking, rides, questions

Is a Trial Right For Me Right Now?

Use this checklist when searching for clinical trial options:

- ☐ I know my biomarkers and genetic syndromes
- ☐ I understand my current treatment options
- ☐ I understand prior treatments I've used
- ☐ I've found trial options for my stage and specific mutations
- ☐ The trial schedule fits into my life (travel, time, cost)

Find Trials That Fit Your Lifestyle

These resources can help you understand the requirements and assist in your search for trials.

Sign up for our Clinical Trials Newsletter fightcrc.org/trialnews

Find a NCI-Designated Cancer Center Locate nearby academic cancer centers that run multiple trials. (Useful if you can travel.)

NCI Trial Help (free live assistance) Speak with an information specialist (English/Spanish) to build a custom list you can review with your doctor. Call 1-800-4-CANCER or visit LiveHelp.cancer.gov to chat

ClinicalTrials.gov The full U.S. registry for all sponsors; search trials using the available filters (condition, location, recruiting status, biomarkers).

Your care team Ask your oncologist, nurse, or navigator to search with you and confirm eligibility.

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Insurance Coverage

Plan routine patient costs in approved/qualifying trials

Medicare Covered; complications covered; Medicare Advantage routes routine costs to Original Medicare.

Private (Affordable Care Act) Most non-grandfathered plans must cover routine patient costs (grandfathered plans may be exempt).

TIP Ask the coordinator for a written list of covered vs. non-covered costs.

Your Rights

- You choose whether to join. Your regular care continues either way.
- You can stop at any time.
- You'll be told about potential risks and benefits.
- Your information is protected. Oversight includes an IRB, and many studies also have a DSMB for ongoing safety monitoring.

Medically reviewed by Cathy Eng, MD, FACP, FASCO.
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