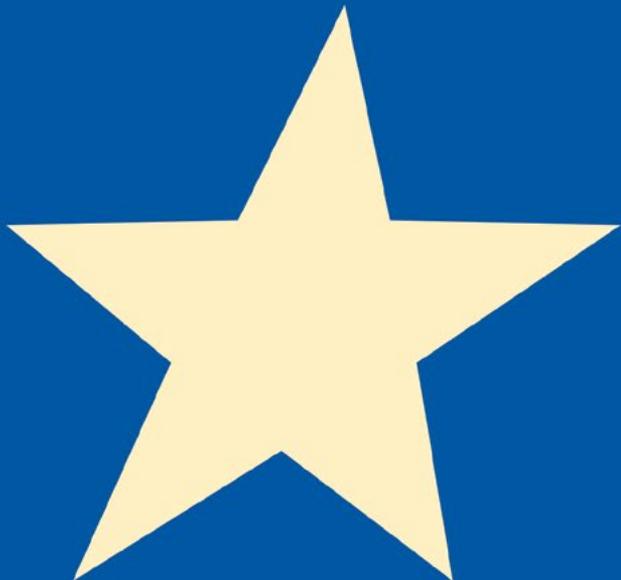


F!GHT
★
COLORECTAL CANCER



CLINICAL TRIALS
All the Things You Want to Know and More

CLINICAL TRIALS

This resource is designed to inform you about clinical trials. In this magazine, you will learn how clinical trials work, how they advance treatment and care for cancer patients, questions to ask when considering clinical trials, patient stories, and more!

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COVER:
Tom Marsilje, Ph.D.
Stage IV fighter

FIGHT CRC

ABOUT FIGHT COLORECTAL CANCER

We FIGHT to cure colorectal cancer and serve as relentless champions of hope for all affected by this disease through informed patient support, impactful policy change, and breakthrough research endeavors.

MEDICAL DISCLAIMER

The information and services provided by Fight Colorectal Cancer are for general informational purposes only and are not intended to be substitutes for professional medical advice, diagnoses, or treatment. If you are ill, or suspect that you are ill, see a doctor immediately. In an emergency, call 911 or go to the nearest emergency room. Fight Colorectal Cancer never recommends or endorses any specific physicians, products, or treatments for any condition. This mini magazine does not serve as an advertisement or endorsement for any products or sponsors mentioned.

FEATURED ADVOCATES

Throughout this magazine, you'll encounter tips and stories from a handful of colorectal cancer advocates who have real experiences with clinical trials.



As the world looks towards a future without cancer, many are working hard to learn about the disease: how it works, how to best treat it, how to detect it, and how to make those who have it live longer and with more comfort. This work is most successful when teams of patients and researchers come together in clinical trials – a necessary step to achieving a world without cancer.



CLINICAL TRIALS DEFINED

CLINICAL TRIALS ARE RESEARCH studies. The goal of clinical trials is to make cancer treatment better so people can live longer. Researchers and doctors follow strict guidelines to protect trial participants (page 21) while collecting information to assess medical protocols, treatments, medical devices, and more. They do this to learn if they work and if they are safe. Clinical trials are done for many diseases – including colorectal cancer (CRC) – and within different groups of people (age, ethnicity, sex). Before new drugs reach patients enrolled in clinical trials, they go through a rigorous testing process.

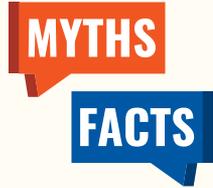
For CRC, clinical trials provide information on new, innovative ways to treat the disease. Without them, CRC therapies would not evolve to become better and more reliable. All current therapies used today are a result of clinical trials!



VOCABULARY

- **Standard of Care:** Also called best practice, this is a leading treatment protocol used by medical professionals to treat a certain disease.
- **Protocol:** A detailed plan that describes the steps of a clinical trial or treatment.
- **Informed Consent:** The process which a person is informed of the purpose, methods, and risks of a procedure, and then agrees to receive treatment.

COMMON CLINICAL TRIAL MYTHS



MYTH: If I join a clinical trial, I'll get a sugar pill.

FACT: According to Dr. Edith Mitchell, "no patient will receive less than standard of care." (Read more on page 18). All patients on trials receive a form of cancer treatment.

MYTH: Clinical trials cost too much money.

FACT: Clinical trial therapies are generally paid for by the sponsor of the trial. The standard of care treatments, like lab work, are often paid by your insurance company. Ask your doctor who will pay for each step of your trial.

MYTH: Clinical trials are hard to find.

FACT: This myth can be true, however there are many new resources to help you search for clinical trials, including the Fight CRC Clinical Trial Finder. To learn more about these online tools, check out page 14. In addition, your doctor may be able to connect you to a clinical trial in your area. If your doctor does not know of any clinical trials, seek a second opinion from another doctor to inquire about clinical trials.

"I know the clinical trial system is intimidating but don't give up! There are now a number of online resources available to help you navigate the clinical trial system and make it as easy as possible. One such resource I work on is 'Tom's Trials 4 CRC' - a part of the Paltown family of patient support websites." More on page 22.

– Tom Marsilje, Ph.D.
creator of the Fight CRC Clinical Trial Finder
(previously the Late Stage MSS-CRC Trial Finder)

MYTH: Trials are my last option.

FACT: There are many trials available to patients with different stages, and along the cancer continuum, not just those who have not responded to treatment. (Read more on page 12)

MYTH: I'll be a guinea pig.

FACT: A tremendous amount of research has already been done on the drugs used in clinical trials (see page 7). While on a clinical trial, you will likely receive excellent care, be monitored thoroughly and be treated with respect.



ADVANCES IN TREATMENT OPTIONS CANNOT HAPPEN WITHOUT PATIENTS

LESS THAN 5% OF ADULTS with cancer will join a clinical trial. According to the American Cancer Society (ACS), the five-year survival rate for stage IIIb CRC is 69% and for stage IV CRC, about 11%. Clinical trials can help increase these percentages by comparing standard of care with new drugs and treatment protocols that could prove to be better.

About 60% of children with cancer participate in clinical trials. According to CureSearch for Children's Cancer, in the last 40 years, the overall survival rate for children's cancer has increased from 10% to nearly 90% today. For many rare childhood cancers, the survival rate is much less.

"In the time that I've been a cancer researcher, I've seen clinical trials benefit the adult cancer community. For example, non-small cell lung cancer and melanoma have had their standard of care therapies completely changed in the past 10 years based upon very successful clinical trials. There are now many survivors of those two cancer types that are currently alive with good quality of life for years longer than would have been the case for them just 10 years ago."

Tom Marsilje, Ph.D.



▶ To support research efforts:
Give.FightCRC.org

YOU ARE IN THE DRIVER'S SEAT!

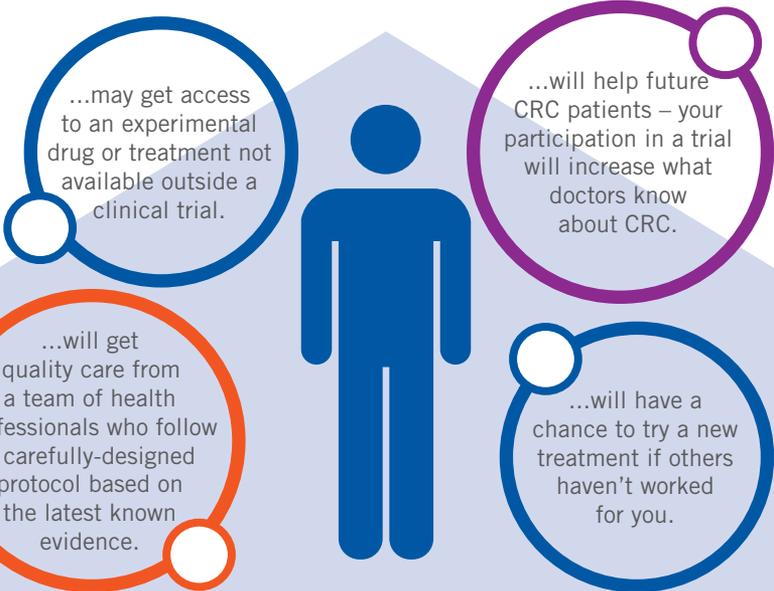
CLINICAL TRIAL PARTICIPATION is **voluntary**. Before joining, you will voluntarily sign an **informed consent** – a detailed document with all of the trial information. You can withdraw from the trial at any time, if you choose to do so. To join a clinical trial, you're required to meet the trial's eligibility based on specific medical criteria. For example, researchers may be recruiting patients of a certain age, with a tumor in a specific location or who have a certain genetic mutation (see page 17).

While participating in a clinical trial does not guarantee a cure for your cancer, by participating, you...

"Nobody is more interested in saving your life than YOU are. If you're not prepared for that, then reach out to others, and get prepared to learn about your condition and your options. The information you need is out there-- somewhere! Find it, or get someone close to you to help you to find it."

- Celine Ryan

GETTING A SECOND OPINION is common. Don't be shy about asking, and don't worry about offending your doctor. The top priority is making sure YOU have access to the best treatment for YOU, even if it means taking a little extra time before beginning your treatment. Second opinions may provide more education on your cancer and treatment options, including clinical trials, to consider.



...may get access to an experimental drug or treatment not available outside a clinical trial.

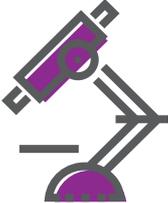
...will help future CRC patients – your participation in a trial will increase what doctors know about CRC.

...will get quality care from a team of health professionals who follow a carefully-designed protocol based on the latest known evidence.

...will have a chance to try a new treatment if others haven't worked for you.

HOW SAFE ARE THEY AND HOW WELL DO THEY WORK?

ON AVERAGE, IT TAKES A NEW CANCER DRUG eight years to get through clinical trials. There are many phases a new drug or protocol goes through to ensure safety before doctors can use it to treat patients.

		
<p>PRECLINICAL</p>	<p>PHASE 1</p>	<p>PHASE 2</p>
<p>Preclinical research is not done on humans.</p>	<p>THE DOSE</p>	<p>DOES IT WORK?</p>
<p>Doctors clearly describe why their trial may work. This occurs before people are invited to participate.</p> <ul style="list-style-type: none"> • TIME: about 6 years <p>An investigational new drug application is often needed to learn about preclinical work, how the drug is manufactured, and more.</p>	<ul style="list-style-type: none"> • determine safe dose range • identify side effects • TIME: 3 months – 1 year • less than 30 participants <p>Doctors slowly increase drug amount to find a safe dosage that doesn't lead to severe side effects.</p> <p>Doctors learn how the drug is absorbed by the body, which affects drug delivery. (For example, is it better to take the drug intravenously or orally?)</p> <p>*There have been times when Phase 1 trials slowed or stopped cancer growth.</p>	<ul style="list-style-type: none"> • evaluate safety • evaluate effectiveness • TIME: 2 years • 30 – 120 participants <p>Doctors collect more safety information. They learn if the treatment works by taking blood analysis or tumor measurements.</p> <p>Patients may receive different doses of the new treatment to see which dose is best.</p>

	
	
<p>PHASE 3</p>	<p>PHASE 4</p>
<p>HOW WELL IT WORKS</p>	<p>ONGOING</p>
<ul style="list-style-type: none"> • confirm effectiveness • monitor side effects • compare to standard of care • gather as much information as possible • TIME: about 2 years • about 300 participants <p>Doctors learn if the new treatment is better than the old, or if it has fewer side effects and is equally effective. These are randomized (page 11) for comparison.</p> <p>If the new protocol or drug is beneficial, doctors can apply for FDA approval.</p>	<ul style="list-style-type: none"> • gather information on the treatment's effect in different demographics • collect information on side effects that result from long-term use • TIME: many years • various number of participants <p>If the FDA approves a new drug or protocol, studies continue so doctors can learn about the long-term effectiveness and side effects.</p>

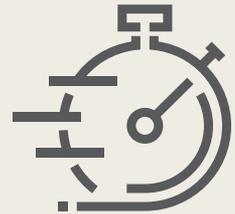
1 in 5

About one in five new drugs that enter clinical trials receive FDA approval



VOCABULARY

Effectiveness refers to whether or not something works.



From time to time, you may hear about trials that were accelerated for FDA approval. This means that drugs for serious conditions, which fill an unmet need, can request faster approval.

KAREN'S EXPERIENCE WITH CLINICAL TRIALS



METASTATIC (STAGE IV, OR “LATE-STAGE”) means the cancer spread beyond the place it started. The outlook for late-stage patients is poorer than those diagnosed with an “early stage” cancer (stages I & II). Stage IV CRC is often challenging to treat. In Karen's case, the cancer spread to her right adrenal gland, with questionable spots on her liver.

Karen was treated at a National Cancer Institute (NCI)-designated research center where her oncology team treated the cancer aggressively. She underwent pelvic radiation 5 times a week for 5 weeks. She took the chemotherapy drug capecitabine (Xeloda®), followed by 7 rounds of the chemotherapy combination oxaliplatin and capecitabine.



Karen Wheling
Stage IV survivor

decreased her primary tumor size by 75%. Chemo stabilized the tumor but didn't remove it. She felt hopeless.

Several months after diagnosis and initial treatment, her oncologist discussed a clinical trial. Until then, she didn't know a trial could be an option.

“Since I had a BRAF mutation, they wanted me to join a small phase 1 trial for CRC patients... I decided to go for it.”

“I received these medicines because they were considered the standard of care, but the side effects were terrible... my quality of life went down.”

Treatments for Karen were arduous, with serious side effects. Over time doctors questioned if they were her best option. The radiation therapy

Her BRAF mutation (that only 5 - 10% of CRC patients have) made her eligible for a targeted therapy drug combination that was successful in melanoma patients with the BRAF mutation, with noticeably less side effects.

Following many talks with her oncologist, Karen joined the trial.

“The decision was totally mine. I wanted fewer side effects, my cancer was at a standstill, I was willing to try. Also, I knew ahead of time I would get the new treatment.”

While on the trial she received regular EKGs and blood work, occasional ultrasounds of her heart, visual skin evaluations and CT scans. Living just 30 minutes away from her cancer center made travel relatively convenient.

“The quality of care I had at the cancer center was amazing, but once I joined the trial, it went up a notch. I was on a phase 1 trial – they wanted to monitor me closely and take precautions.”

Her medical team was available to answer any questions and provide detailed information about the trial and the science behind it.

Although the experience of going onto the trial drug was positive and the treatment caused zero side effects, it failed. Scans showed her tumor growing. She was promptly removed from the trial. Doctors continued to follow up with her and resumed standard of care.

Although a challenging circumstance, Karen is happy about her clinical trial experience.

“I’m happy to say this failure increased understanding in the medical and research community. Now we know the BRAF mutation for CRC proliferates through more than one pathway. Researchers



VOCABULARY

Quality of Life: General wellbeing and satisfaction

now conduct clinical trials using targeted therapy drugs similar to what I took, but they now add a second chemo in hopes of cutting off the path to cancer proliferation.”

Karen remains hopeful and willing to join future trials. To other patients considering a trial, she recommends:

- **Get as much information about the trial as possible**
- **Understand how the trial may help more than the standard of care**
- **Learn about the side effects and their impact on quality of life**
- **Discuss the trial with your medical team and/or the medical team involved with the clinical trial**
- **Be your own advocate**

Karen had surgery one year after her clinical trial ended and doctors declared no evidence of disease (NED) – a status she’s maintained for over five years.

"WHY CAN'T I PICK MY TREATMENT OPTIONS?"

THERE ARE MANY TYPES OF clinical trial designs. One type, called a randomized clinical trial (RCT), is often considered best scientific practice. Some phase 2 and all phase 3 trials are randomized. This means participants are divided into groups. One group gets the standard of care while the other gets the new treatment, with or without the standard of care. This allows the groups to be compared.



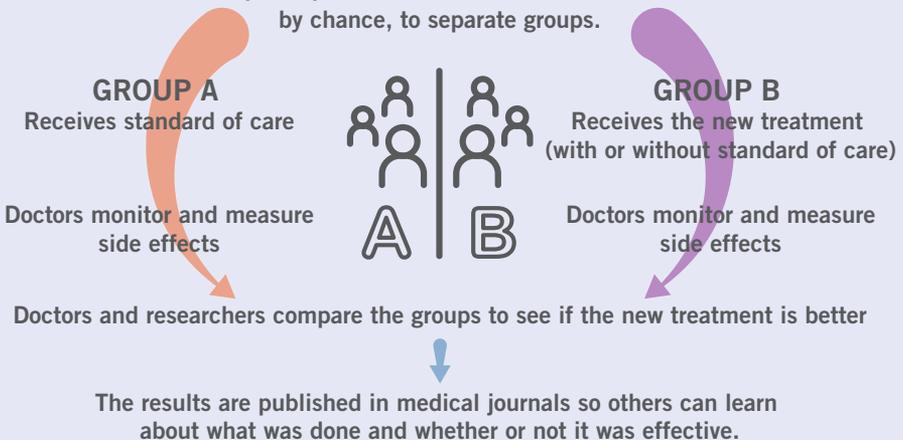
VOCABULARY

Blind Trial: when participants don't know which group they're in.

Double Blind Trial: when participants and doctors don't know which participants are in which group. This is done to remove any bias from the trial.

In determining which group you'll be in, think of flipping a coin: the chance of getting heads is the same as getting tails. Randomization is done to reduce the potential of biases or judgments, making the study more reliable.

Trial participants are selected and randomized, by chance, to separate groups.



TRIAL TYPES & TRIAL TERMS

COLORECTAL CANCER PATIENTS diagnosed at any stage can find clinical trials, and clinical trials. Options exist, no matter if you've had treatment for cancer or not.

Treatment Trials · test new drugs and treatment protocols

Prevention Trials · look for new and innovative ways to prevent cancer and/or cancer recurrence

Screening Trials · identify the best ways to screen for cancer, and develop new ways to screen for cancer (think colonoscopy)

Adjuvant Trials · done right after primary treatment to reduce the chances of cancer coming back or spreading after primary treatment

Neoadjuvant Trials · done right before primary treatment to reduce the chances of cancer coming back or spreading after primary treatment

Single Agent Trials · test only one drug

Combination Trials · test multiple (more than one) drugs being used together

Quality of Life / Supportive Care Trials · discover ways to make patients more comfortable during treatment and with fewer side effects

Diagnostic Trials · attempt to improve the way tests identify whether or not a person has cancer

MEASURING CLINICAL TRIAL SUCCESS

Clinical trials differ in how they measure success, but here are some terms you might hear:

Overall Survival ·

The length of time from the date of diagnosis or the start of treatment that patients are still alive

Disease Free Survival ·

the length of time that cancer has disappeared

Progression Free Survival ·

how long after treatment starts that the cancer begins to grow

Complete Radiographic Response · after treatment, all signs of cancer are gone

Partial Radiographic Response ·

there is still some sign of cancer after treatment, but it has decreased

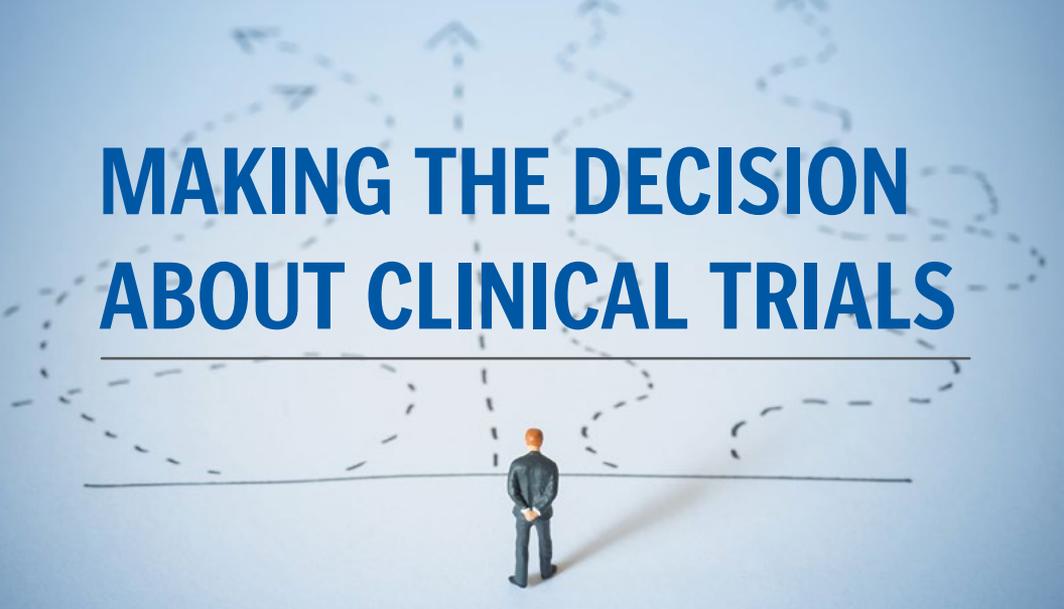
Pharmacokinetics ·

how long does the drug stay in the patient's system

Pharmacodynamics ·

the body's response to the drug - does the drug hit its desired target?

MAKING THE DECISION ABOUT CLINICAL TRIALS

A photograph of a small figurine of a person standing on a solid horizontal line that represents a path. From this line, several dashed lines branch out in various directions, creating a complex network of paths. The background is a light blue gradient.

DECIDING WHETHER OR NOT TO JOIN A CLINICAL TRIAL can take time and a lot of consideration. This decision shouldn't be taken lightly. It can feel overwhelming. Take your time and follow these steps to help you along:

1 **Tell** your doctor you're interested in learning about clinical trials. Your doctor can help identify trials that may be a good fit for you.

2 **Gather** the following medical history information and keep it together. This will keep you organized in determining your trial eligibility.

- The kind of cancer you have (colon or rectal), the stage, where it started
- Pathology report (if you don't have it, ask for it)
- Size of the tumor

- Information about any previous cancer diagnosis
- List of treatments you've had for cancer with dates (current or previous cancer)

“Talking to your support team and asking for help can be tremendously important. Friends and family have been very supportive, offering to drive me to and from appointments and to help with taking care of the house and our dogs. My mother-in-law always stays with us for a few days whenever I get treatment.”

– John MacLeod

3 Talk to your support team.

Talking to your loved ones about clinical trials should not be overlooked. Good communication often leads to increased support, encouragement and help with decision making. Consider bringing someone with you to your appointments so they can help you clarify and retain information. In addition, while reading through various clinical trials, ask a family member or friend for their help – if both of you read the same trial, you can help each other understand the ins and outs of the study and make a better decision.

Making a decision about clinical trials can be difficult, even stressful. If you experience stress or anxiety, don't hesitate to reach out to your social worker or mental health provider. They can help you manage the added stress. Remember, your support team is there to help you!

4 Explore online clinical trial finders to find one that's right for you!

- **ClinicalTrials.gov** lists all phase 3 and most phase 2 trials. The FDA requires them to be listed on this website.

“The time to do a trial is when you, the patient, think it is time (providing that you qualify for one). Things to consider: time, expense, distance, and how your life will be impacted in the event the trial does not work for you.”

- Celine Ryan

- **Fight CRC Clinical Trial Finder: A curated list powered by patients**

is a one-stop place to find high-impact clinical trials for stage IV CRC patients. Search features allow you to look for trials in your area and trials that match your particular tumor type. This trial finder emphasizes the relationship between your values and desire to find clinical trials that will have a meaningful impact on your treatment. It is curated and reviewed by Fight CRC's staff, medical experts, and research advocate volunteers.

- **EmergingMed** lists available trials for colorectal cancer. You can also call **866-278-0392** to speak to a Clinical Trial Navigator (a live person) for direct assistance.
- **Smart Patients** lets you search for and browse colorectal cancer clinical trials online. You can also join the Smart Patients colorectal cancer community where patients and families affected by colon, rectal, or anal cancer learn from each other.





- **Antidote** works by having you answer a few questions before the tool creates a list of trials most relevant to you. If you have questions about any of the trials, please contact the study coordinator listed for the trial. This free, confidential, personalized service helps you understand which clinical trials may be an option for you.

- **Colontown** is an online community of over 60 “secret” groups on Facebook for CRC patients, survivors, and caregivers. There are separate neighborhoods focused on patients with different stages of disease, the differing types of treatment, and special interests – such as CRC clinical trials, young-onset CRC patients, and local support groups. “TOM’S TRIALS” neighborhoods are a place where patients share both curated, scientific information and personal, patient experience with current clinical trials.

5 **Read** the protocols that interest you.

6 **Ask** your medical team questions to clarify the clinical trial protocols:

- Am I eligible for this trial?
- How do the possible risks of the new treatment compare with others?
- Are there extra procedures or doctor visits?
- Who pays for what?
- What is the standard treatment for someone in my situation?
- What is the purpose of this clinical trial?
- Will I have to travel or stay overnight in the hospital?
- What will my treatment schedule be?
- What are the short-term and long-term side effects?
- How will my health be monitored during treatment?



TIPS FROM PATIENTS



“Take a deep breath and compare your treatment options using data to guide your decision. For example, right now there is an experimental therapy with preliminary higher response rates than multiple FDA-approved therapies for CRC. So an experimental therapy does not automatically mean a lower quality therapy than FDA-approved options. Being an experimental therapy just means it has been taken by fewer patients, so less is known about its safety & efficacy profile.”

- **Tom Marsilje, Ph.D.** | *Stage IV fighter*

“Here’s my truth: I’m not going to take this lying down! Participating in clinical trials is the only hope for most of us. We have to find better treatments! It’s up to each of us to find them through clinical trials. We must be willing to travel to places that have clinical trials. Do it sooner than later. I’ve lost too many friends to this disease.” - **Amy Joosten-Butler** | *Stage IV survivor*



“Considering a clinical trial is a great thing. For one, it could give you longer life, invoke hope and help keep hope alive. Being in a trial could provide additional information that can help others down the road. But, I don’t recommend listening to other people’s advice. You can talk to them about their experiences, sure – but it’s better to listen to how you feel. Remember that everyone is different, every body will react differently to different treatments. Talk it over with your family and friends, but don’t base your decision on what someone else is doing or has done.”

- **Trina Lashawn** | *Stage IV fighter*

“Take your time when choosing a trial, and consider all the ways it can affect your day-to-day. There are lots of impacts from clinical trials. The side effects are often unknown, appointments can significantly alter [your] family’s schedule, often travel is required to get to the site of the trial, [which could be a significant added cost]. Immunotherapy trials are very scary for stage IV patients. Receiving an immunotherapy drug can make patients ineligible to receive immunotherapy drugs ever again as part of a trial. So picking the ‘right’ trial is literally a life and death decision!” - **John MacLeod** | *Stage IV fighter*



“If you’re considering a trial, understand that you must be in relatively good health. Sometimes patients wait until they have had so much chemo that they are no longer healthy enough to do a trial.

This is a heart-breaking situation, and many assume that a trial is waiting for them when they are ready. The problem with that line of thinking is that your body AND your will have to both be “ready” at the same time. If your body is too damaged, even though you think you are now ready for a trial, you may not be eligible for one.” - **Celine Ryan** | *Stage IV survivor*

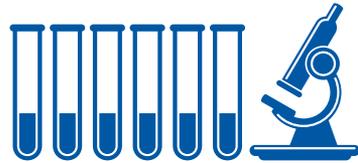
BIOMARKER (TUMOR) TESTING

NOT ALL COLORECTAL CANCER is the same! **Biological markers**, or **biomarkers**, are different for each patient and could affect the way your body reacts to certain treatments. Biomarkers are used by oncologists to determine personalized treatment strategies (**personalized medicine**).

Biomarker testing is important for all CRC patients because the results can affect your treatment decision. Make sure your doctor tests your tumor at diagnosis.

Some clinical trials require a certain biomarker expression for eligibility. Ask your doctor to test your tumor before making treatment decisions.

To learn more about biomarkers, visit: [FightCRC.org/Biomarked](https://fightcrc.org/Biomarked)



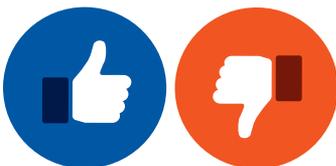
CLINICAL TRIAL RISKS

PROTECTING CLINICAL TRIAL patients is the most important part of a trial – after all, clinical trials are done to improve cancer treatment. However, some trials test new drugs with unknown side effects and reactions. Even drugs used for many years cause severe or life-threatening side effects in some people. There have been many successful trials, however, there is no guarantee all trials will be successful.

Trial procedures are reviewed by researchers, their peers, Institutional Review Boards (IRBs), patient advocates, the National Cancer Institute (NCI), the FDA, and more to ensure patient safety. Even with all the dedicated review, there are still risks.

Here are some considerations:

- 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 may be worse than the standard treatment.
- Patients in RCTs can't choose their treatment, nor can their doctors.
- Some clinical trial costs may not be covered. Check with your insurance company to learn more about potential costs.
- If the trial requires you to travel, consider additional challenges that may result. For example, costs of hotels, drive or flight time, time spent away from home, etc.



To manage your side effects, download the Side Effects Mini Magazine: [FightCRC.org/SideEffectsMM](https://fightcrc.org/SideEffectsMM)

AN EXPERT SPEAKS OUT ABOUT CLINICAL TRIALS



EDITH MITCHELL, M.D., is Clinical Professor of Medicine and Medical Oncology and Program Leader in Gastrointestinal Oncology at Thomas Jefferson University. She holds the positions of Associate Director of Diversity Programs for the Kimmel Cancer Center at Jefferson and Director of the Kimmel Cancer Center to Eliminate Cancer Disparities. She belongs to many oncology groups and serves on the National Cancer Institute Review Panel and the Cancer Investigations Review Committee.

Dr. Mitchell spoke with Fight CRC about clinical trials.

Q: Dr. Mitchell, you've been an oncology researcher for many years and have received over 20 cancer research and principal investigator awards. How do you talk to patients about participating in clinical trials?

Dr. Mitchell: I tell them that for every medication we use, clinical trials have been conducted, and those who participate in clinical trials have the advantage of early involvement with new drugs. Even over-the-counter medications in drug stores have gone through trials to monitor side effects – even Tylenol®, which is in about 90% of patients' homes.

I explain the trial phases (see page 7). If there's a randomization, I make sure they know they have a

50% chance of getting standard of care or standard of care plus new treatment. No patient will receive less than standard of care. Clinical trials are *not* below the standard of care.



Edith Mitchell, M.D., FACP

Finally, I ensure the patient really understands the process of the clinical trial and make sure they feel comfortable participating.

Q: As the Director of the Kimmel Cancer Center to Eliminate Cancer Disparities, do you think there is a lack of diversity in clinical trial participation?

Dr. Mitchell: Yes. There are multiple reasons for disparities among racial, ethnic and

underserved groups in relationships to clinical trials. It is not the fault of the patient. Many physicians do not understand, nor do they practice cultural competence when addressing clinical trials.

For example, data has shown that some providers spend less time with black patients – they don’t order tests or offer clinical trials due to the assumption that black patients won’t participate. Certainly, there are cultural issues that may prevent some patients from being interested in a protocol – but a culturally competent staff is always needed to talk to patients.

Q: Can you give an example?

Dr. Mitchell: I had a newly diagnosed rectal cancer patient who had rectal bleeding for several months. He passed out and was brought to the emergency room. ER doctors started fluids and were going to transfuse blood, at which point the patient became belligerent and wouldn’t let them proceed. I was asked to help.

In speaking with the patient, I learned he’s a member of a religion that doesn’t accept blood products. As a doctor, I respect the patient decision and confirmed he didn’t have to receive the transfusion. I ordered IV and other treatments. He did okay, got his surgery a few weeks later and eventually went on a clinical trial. The point is, nobody talked to him about his cultural, or in this case, religious concerns when he refused the transfusion. Nobody asked him why. He lacked



VOCABULARY

Cultural Competence is the ability for medical teams to deliver healthcare services that meet social, cultural, and linguistic needs of patients.

confidence and trust in the team until someone stepped in to learn about his needs, preference, and cultural experiences. Medical institutions need to seek to know the population they serve and have medical care tailored to their findings.

Doctors need to make patients feel comfortable in knowing their best interest is at heart. Then clinical trial participation will increase. Also, giving patients the opportunity to participate – no matter their race, religion, culture or gender. Many patients want trials.

Q: How have you been affected by clinical trials?

Dr. Mitchell: Since I was an intern, I have participated in clinical trials. I’ve seen firsthand the improvement in healthcare outcomes as a result of them, especially the advances in colorectal cancer treatment. I am very big on getting patient participation in trials and dedicated to keeping patients informed.



ORGANIZATIONS COMMITTED TO CLINICAL TRIAL SAFETY



Organizations Committed to Clinical Trial Safety:

- **Institutional Review Boards (IRBs):** Groups of medical experts, scientists, patient advocates, and more who ensure trials are ethical. IRBs are always available to be contacted by trial participants.
- **Data Safety Monitoring Boards (DSMBs):** These track all clinical trial information (data) coming in (mostly phase 3). If issues arise, protocols are quickly adjusted.
- **Principal Investigator (PI):** The person in charge of tracking side effects and patient safety.
- **Office of Human Research Protections (OHRP):** Government agency that ensures patient safety in clinical trials.
- **Federal Drug Administration (FDA):** Government body that decides if a phase 3 clinical trial can go on to the public.
- **Health Insurance Portability and Accountability (HIPPA):** Researchers need to review patient medical records prior to and during clinical trials, which requires patient approval. A document that details the medical records needed, and who will see them, is presented to the patient who is asked to voluntarily authorize the sharing of their records.

*This is not an all-inclusive list.

A Brief History of Clinical Trials and Ethics

Modern clinical trials have been around since 1716, and since then, through various laws, regulations and reports, have become the trials we know today. They follow strict guidelines for patient protection and safety. Clinical trials require voluntary consent, require new drugs be proven safe prior to public use, require federal oversight of drug testing and consent, require measures to ensure protection of clinical trial participants, stress that no one be subjected to cruel, degrading treatment or punishment, and ensure there is a sound standard for ethical conduct in research and medicine.



The Nuremberg Code, the Declaration of Helsinki, the Belmont Report, and the U.S. Code of Federal Regulations give researchers guidelines to respect and protect the rights and welfare of those participating in human research and clinical trials.

AT THE END OF THE DAY, it's YOUR decision whether or not you join a clinical trial. You deserve the opportunity to learn more about clinical trials. Talk to your doctor and make the choice that's best for YOU!

Fight Colorectal Cancer is a trusted, nonprofit advocacy organization dedicated to empowering patients to be their own health advocates.

RESEARCH

At Fight CRC, we fight to make breakthrough research a reality. We fund innovative research grants, convene meetings with national and global experts on the biggest issues in CRC, and we train survivors and caregivers to be a part of scientific discussions. To get involved in research and stay up to date on the latest scientific breakthroughs, follow [@FightCRC](#) on Twitter, or visit us at [FightCRC.org/research](#).

ADVOCACY

Are you ready to turn your pain into purpose? By sharing your story and raising awareness, you can help change policy around colorectal cancer. That's what the Fight CRC Advocacy Program is all about! We advocate on Capitol Hill. We engage and teach grassroots advocates like you to get involved in your communities. To learn more about how to raise your voice for CRC advocacy, visit [FightCRC.org/action-center](#).

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RESOURCES

To download or request print materials, go to: [FightCRC.org/Resources](#)

- **COLONTOWN@ – a PALTOWN, PEER-CURATED COMMUNITY.** This is a group of online communities on Facebook, which includes "TOM'S TRIALS." Here, patients share both curated, scientific information and personal, patient experience with current clinical trials. Visit: [colontown.org](#)
- **Cancer Support Community: Our partnership with Cancer Support Community provides a free call line available in English and Spanish. Live assistance is available from 9 a.m. – 9 p.m. ET Monday through Friday. The call line does not offer medical advice, but is for informational purposes only.**

REFERENCES

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- <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html>

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