Clinical Trials: What You Need to Know

Knowing all you can about clinical trials can help you feel more certain when deciding whether to take part in one. The information in this section addresses many questions and concerns about clinical trials. It can help prepare you to discuss the pros and cons with your doctor and your family and decide whether being in a clinical trial is right for you.

Types and Phases of Clinical Trials

- Phase IV clinical trials: What else do we need to know?

Clinical trials are studies to test new drugs, already approved drugs, devices, or other forms of treatments. Many clinical trials look at new ways to detect, diagnose, or measure the extent of disease. Some even look at ways to prevent diseases from happening. Researchers still use human volunteers to test these methods, and the same rules apply.

Doctors use clinical trials to learn whether a new drug, treatment, or combination works and is safe to use for people. Clinical trials are important in developing new treatments for serious diseases like cancer. All new treatments must go through clinical trials before being approved by the Food and Drug Administration (FDA). Cancer clinical trials can take years to complete. It can take months, if not years, to see if a cancer treatment does what it is meant to do.

Why do we need clinical trials?

Clinical trials show us what works (and what doesn't) in medicine and health care. They are the best way to learn what works in treating diseases like cancer. Clinical trials are designed to answer some important questions:

- Does the new treatment work in people? If it does, doctors will also look at how well it works. Is it better than treatment now being used? If it's not better, is it as good and cause fewer side effects? Or does it work in some people who aren't helped by current treatments?
- Is the new treatment safe? No treatment or procedure – even one already in common use – is without risk. But do the benefits of the new treatment outweigh the risks?
- Is this treatment better than the standard treatment given for this disease? Clinical trials help show if a new drug or treatment, or a new treatment combination, works better than what is now used.

Answering these questions, while giving as few people as possible an unknown treatment, often requires several clinical trials in different "phases." Each phase is designed to answer certain questions while keeping the people taking part as safe as possible. Results from these phases show if the new drug or treatment is reasonably safe and effective.

Pre-clinical (or laboratory) studies

Clinical trials are done only after pre-clinical findings suggest that the new drug or treatment is likely to be safe and will work in people.

Pre-clinical studies, also called laboratory studies, include:

- Cell studies: These are often the first tests done on a new treatment. To see if it might work, researchers look for effects of the new treatment on cancer cells that are grown in a lab dish or a test tube. These studies may be done on human cancer cells or animal cancer cells.
- Animal studies: Treatments that look promising in cell studies are tested next on cancers in live animals. This gives researchers an idea of how safe the new treatment is in a living creature.

Pre-clinical studies give a lot of useful information, but not all that is needed. Humans and mice can be very different in the way they absorb, process, and get rid of drugs or treatments. A treatment that works against cancer in a mouse might or might not work in people. There could also be side effects and other problems that didn't show up when the treatment was used in mice but could show up in people.

If the pre-clinical studies are completed and the treatment still seems promising, the US Food and Drug Administration (FDA) must give permission before the treatment can be tested people.

The investigational new drug (IND) application

Before a clinical trial can be started, the research must be approved. An investigational new drug or IND application or request must be filed with the FDA when researchers want to study a drug in humans. The IND application must contain certain information, such as:

- Results from studies so that the FDA can decide whether the treatment is safe for testing in people.
- How the drug is made, who makes it, what's in it, how stable it is, and more.
- Detailed outlines for the planned clinical studies, called study protocols, are reviewed to see if people might be exposed to needless risks.
- Details about the clinical trial team to see if they have the knowledge and skill to run clinical trials.

The research sponsor must commit to getting informed consent from everyone on the

clinical trial. They must also commit to having the study reviewed by an institutional review board (IRB) and following all the rules required for studying investigational new drugs

Phases of clinical trials

Clinical trials are usually conducted in phases that build on one another. Each phase is designed to answer certain questions. Knowing the phase of the clinical trial is important because it can give you some idea about how much is known about the treatment being studied. There are benefits and risks to taking part in each phase of a clinical trial.

Although there are clinical trials for devices as well as other diseases and treatments, drugs for cancer patients are used in the examples of clinical trial phases described here.

Phase 0 clinical trials: Exploring if and how a new drug may work

Even though phase 0 studies are done in humans, this type of study isn't like the other phases of clinical trials. The purpose of this phase is to help speed up and streamline the drug approval process. Phase 0 studies may help researchers find out if the drugs do what they're expected to do. This may help save time and money that would have been spent on later phase trials.

Phase 0 studies use only a few small doses of a new drug in a few people. They might test whether the drug reaches the tumor, how the drug acts in the human body, and how cancer cells in the human body respond to the drug. People in these studies might need extra tests[1] such as biopsies, scans, and blood samples as part of the process.

Unlike other phases of clinical trials, there's almost no chance the people in phase 0 trials will benefit. The benefit will be for other people in the future. And because drug doses are low, there's also less risk to those in the trial.

Phase 0 studies aren't widely used, and there are some drugs for which they wouldn't be helpful. Phase 0 studies are very small, often with fewer than 15 people, and the drug is given only for a short time. They're not a required part of testing a new drug.

Phase I clinical trials: Is the treatment safe?

Phase I studies of a new drug are usually the first that involve people. Phase I studies are done to find the highest dose of the new treatment that can be given safely without

causing severe side effects. Although the treatment has been tested in lab and animal studies, the side effects in people can't be known for sure. These studies also help to decide on the best way to give the new treatment.

Key points of phase I clinical trials

- The first few people in the study get a very low dose of the treatment and are watched very closely. If there are only minor side effects, the next few participants get a higher dose. This process continues until doctors find a dose that's most likely to work while having an acceptable level of side effects.
- Phase I trials are also looking at what the drug does to the body and what the body does with the drug.
- Safety is the main concern. The research team keeps a close eye on the people and watches for any severe side effects. Because of the small numbers of people in phase I studies, rare side effects may not be seen until later phases of trials when more people receive the treatment.
- While some people may benefit from being on one, disease response is not the main purpose of a phase I trial,
- Placebos (inactive treatments) are not used in phase I trials.
- Phase I trials usually include a small number of people (up to a few dozen).
- Phase I trials most often include people with different types of cancer.
- These studies are usually done in major cancer centers.

Phase I trials carry the most potential risk. But phase I studies do help some patients. For those with life-threatening illnesses, weighing the potential risks and benefits carefully is key. Sometimes people choose to join phase I trials when all other treatment options have already been tried.

Phase II clinical trials: Does the treatment work?

If a new treatment is found to be safe in phase I clinical trials, a phase II clinical trial is done to see if it works in certain types of cancer. The benefit the doctors look for depends on the goal of the treatment. It may mean the cancer shrinks or disappears. Or it might mean there's a long period of time where the cancer doesn't get any bigger, or there's a longer time before the cancer comes back. In some studies, the benefit may be an improved quality of life. Many clinical trials look to see if people getting the new treatment live longer than most people do without the treatment.

Key points of phase II clinical trials

A group of 25 to 100 patients with the same type of cancer get the new treatment in

assigned to the placebo for part of the study will at some point be offered the standard treatment as well.

As with other trials, patients in phase III clinical trials are watched closely for side effects, and treatment is stopped if they're too hard to manage.

Submission for FDA approval: New drug application (NDA)

In the United States, when phase III clinical trials (or sometimes phase II trials) show a new drug is more effective or safer than the current treatment, a new drug application (NDA) is submitted to the Food and Drug Administration (FDA) for approval. The FDA reviews the results from the clinical trials and other relevant information.

Based on the review, the FDA decides whether to approve the treatment for use in patients with the illness the drug was tested on. If approved, the new treatment often becomes a standard of care, and newer drugs may be tested against it before they can be approved.

Van Norman GA. Drugs, devices, and the FDA: part 1: an overview of approval processes for drugs. *JACC Basic Transl Sci*. 2016; 1(3):170-179.

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Deciding Whether to Be Part of a Clinical Trial

Each clinical trial has benefits and risks.46.y1p(6yf 0 0 rg /GS:170-179.)g Tf 0 0 0 rg /GS294 gs 1.5 Ts

- Is there anything else I can read about this clinical trial?
- What kinds of treatments and tests would I need to have? How often are they done?
- Would I need to plan on extra time or travel?
- What side effects might I expect from the trial treatment? Are there other risks? How do these side effects compare to the side effects from standard care for my illness?
- How will we know if the treatment is working?
- Will I have to be in the hospital for any part of the trial? If so, how often, for how long, and who will pay for it?
- Will I still be seeing my regular cancer doctor?
- Will I have to pay for anything? Will my insurance cover the treatment?
- If I am harmed as a result of the research, what treatment will I be entitled to?
- How long will I be in the clinical trial? How long will the clinical trial last?
- Will I still be able to work if I am in the clinical trial?
- Are there reasons I could be removed from the clinical trial? Are there reasons the clinical trial might be stopped early?
- Is long-term follow-up care part of the trial? What would it involve?
- If the treatment is working for me, can I keep getting it even after the clinical trial ends?
- Can I talk to other people taking part in the clinical trial?
- Will I be able to find out about the results of the clinical trial?
- Is there anything else I can read about this clinical trial?

You might find it helpful to include trusted friends and family members in your decision-making process. They might ask questions you hadn't thought of and can help you make sure that you're choosing what's right for you. Also, getting a second opinion[1] from a doctor who's not part of the study may help you decide if a certain study is the best option for you.

Risks versus benefits

Each clinical trial has its own benefits and risks. But for the most part, clinical trials (other than phase 0) have some of the same potential benefits:

- You might help others who have the same disease by helping to advance cancer research.
- You could get a treatment that's not available outside of the trial. This treatment

might be safer or work better than current options.
- This may increase the number of your treatment options.
- You may feel more control by taking a more active role in your health care.
- You'll likely see your cancer care team more often so that they can monitor your disease and check for side effects of the new treatment.
- Some study sponsors may pay for part or all your medical care and other expenses during the trial. (This isn't true for all clinical trials.)

Some possible risks of being in a clinical trial can include:

- The new treatment may have unknown side effects or other risks which might be worse than those from standard treatments.
- The new treatment may not work for you even if it helps others.
- You may need to have more doctor visits or testing which may require more time and travel.
- If you take part in a randomized clinical trial , you may not have a choice about which treatment you get. If the study is blinded, you (and maybe your doctor) won't know which treatment you're getting. (This information will be available to the clinical trial team as needed for your safety).
- Insurers may not cover all costs of the clinical trial. They usually do cover the costs of what would normally be standard care. Be sure to talk to your insurance provider and someone involved with the clinical trial before you decide to take part.

Common concerns about clinical trials

Most people have some concerns about taking part in a clinical trial because they're not really sure what it will mean for them. Get as much information as you need to make the choice that's right for you.

Will there be risks?

Yes, all clinical trials have risks. But any medical test, treatment, or procedure has risks. The risk may be higher in a clinical trial because there are more unknowns. This is especially true of phase I and II clinical trials, where the treatment has been studied in fewer people.

Perhaps a bigger question is if the possible benefits outweigh the risks. People with

cancer are often willing to accept a certain amount of risk for a chance to be helped. But it's always important to be clear on what this chance is. Ask your doctor to give you an idea of what the benefits may be and which is likely for you. Some people may decide that any chance of being helped is worth the risk, while others may not. Others may be willing to take certain risks to help others.

Will I be a "guinea pig?"

You will not be a guinea pig, but it's true that the purpose of a clinical trial is to answer a medical question. People who take part in clinical trials may need to do extra things or have certain tests done as part of the clinical trial.

But this doesn't mean that you won't get excellent care while in the study. In fact, most people enrolled in clinical trials welcome the extra attention they get from their cancer care team.

Studies have shown that people with cancer who felt well informed before they took part in a clinical trial had less regret after the study than those who felt unsure. That's why it's important to take your time, ask questions, and feel good about your decision.

Will I get a placebo?

A placebo is a fake pill or treatment used in some types of clinical trials to help make sure results are from the new treatment or drug. A placebo pill is sometimes called a "sugar pill." Placebos are rarely used alone in clinical trials unless there is no known effective treatment. Most cancer clinical trials do not use placebos unless they are given along with an active drug. It's unethical to give someone a placebo instead of a treatment that's known to work.

There are some types of cancer that no treatments have proven to help. In rare cases, testing a new treatment against a placebo might be needed to prove that the treatment is better than nothing at all. The very least you should expect from any clinical trial is to be offered the treatment standard of care.

Can my doctor or I pick which group I'm in?

Not for studies that are randomized. This means that each person in the study gets assigned by chance to either the treatment group or the control group (who get the best current treatment). Randomization helps decrease the chance that the people in one group will be so different from the other that it could affect outcomes. Randomization helps to make sure that the groups have people in similar states of health, so the results

are not affected by differences between the groups. If people could choose which treatment they got, the study results might not be as accurate.

Some people find the concept of randomized clinical trials distressing, since neither the patient nor the doctor can choose which group the patient is in. This can be especially true if a trial is looking at totally different treatments and a person believes that one is better than the other. But remember, doctors are doing the study because they really don't know which one is better. And sometimes taking part in such a study is the only way a person has a chance of getting a new treatment.

Will I know which group I'm in? Will my doctor know?

The Affordable Care Act[2] requires that health insurance covers the routine patient care costs for people who are in approved clinical trials. **"Routine patient care costs" are costs that would normally be covered for anyone being treated for your kind of cancer.** Insurers are not allowed to drop or limit coverage because a person chooses to take part in a clinical trial. This applies to all clinical trials unless the insurance plan is "grandfathered." (Grandfathered plans are those that a person was enrolled in on or before March 23, 2010 and which has not decreased benefits or increased costs.)

The law requires insurance coverage for phase I, II, III, or IV clinical trials related to prevention, detection, or treatment of cancer or other life-threatening disease if the clinical trial meets one of these requirements:

- It's federally funded (any US federal agency such as the National Cancer Institute, Centers for Disease Control, Department of Defense, etc.)
- It's covered under an investigational new drug application (IND) that's reviewed by the FDA
- It's does not need an IND application.

Insurers do not need to pay for:

- The treatment, device, or service that's being studied. This is usually paid for by the trial's sponsor
- Items and services only needed for data collection and analysis and not used in direct patient care
  Any service that's clearly not in line with standards of care for a certain type of cancer. This is why it is important to know what the clinical trial may not pay for so you can check if your insurance will.

If you're not sure if your trial meets all the requirements, discuss these concerns with your doctor or call Medicare (1-800-633-4227).

Medicaid coverage for clinical trials

As of January 1, 2022, a new law requires that all state Medicaid plans cover the routine patient care costs for members who are in qualifying clinical trials.

Cancer clinical trials must meet certain criteria to be a qualifying clinical trial. Clinical trials must focus on the prevention, detection, and treatment of cancer or another life-threatening disease. The clinical trial must also be approved, done by, or paid for by certain government agencies or other accepted group.

If you're not sure whether the trial you're considering is a qualifying clinical trial, talk with your doctor or contact your state Medicaid agency[3].

What you can do to find out more about costs

Gather as much information as you can about the clinical trial and contact your insurance provider to find out about payment. Many insurers may not be able to give you a simple yes or no answer, because they may review claims on a case-by-case basis. They'll also want to be sure that the doctors supplying the main part of your cancer care are "in network."

If your insurance will not pay for parts of the clinical trial, ask your doctor or the research coordinator about other options. Sponsors may be willing to cover some of the costs your insurance does not.

Should I agree to take part in a clinical trial?

This can be a very tough question. The answer won't be the same for everyone. When trying to decide, first ask yourself some questions.

- Why do I want to take part in a clinical trial?
- What are my goals and what do I expect if I decide to take part? How realistic are these?
- How sure are my doctors about my future if I decide to take part (or not take part) in this clinical trial?
- Do I have all the information I need to make an informed decision?

- Have I weighed the benefits against the risks?
- Have I thought about other factors, such as travel, time, and money?
- Have I looked at my other options?

Some of these questions may not have clear answers but should help you start thinking about these issues. Each person's situation is unique, and each person's reasons for wanting or not wanting to take part in a trial may be different.

Hyperlinks

1. www.cancer.org/cancer/managing-cancer/finding-care/seeking-a-second-opinion.html
2. www.cancer.org/cancer/financial-insurance-matters/health-insurance-laws/the-health-care-law.html
3. www.medicaid.gov/about-us/beneficiary-resources/index.html#when2contactstate

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https://www.nih.gov/health-information/nih-clinical-research-trials-you. Reviewed October 20, 2017. Accessed July 29, 2020.

Last Revised: August 22, 2022

Protecting People in Clinical Trials

Several safeguards are used to help protect people who take part in clinical trials. There are still risks involved with any study, but these safeguards try to reduce the risk as much as possible.

IRB for review. The IRB must decide if the study looks at a worthwhile question and ensures the safety of the people on the trial.

The IRB also makes sure that the informed consent[1] form that people sign before going on a trial is accurate, complete, and easy to understand. Once a clinical trial begins, the IRB watches over it to look for problems. If you are in a clinical trial, you can contact the IRB with any questions or concerns.

Data safety monitoring boards (DSMBs)

Data safety monitoring boards (DSMBs) are used for phase III (and some earlier phase) clinical trials. The job of the DSMB is to watch the progress and results of the clinical trial. The DSMB can stop a clinical trial before it is done if:

- It becomes clear that the new treatment is much more (or much less) effective to allow all people on the clinical trial to get the better treatment
- Safety concerns come up, such as risks being much greater than benefits, so that no one else is exposed to possible harm.

The clinical investigator

The clinical investigator is in charge of all parts of a clinical trial. In some settings this person is called the principal investigator, or PI. The main responsibility for patient safety in a clinical trial belongs to the clinical investigator. This includes letting the study sponsor know right away when severe side effects occur.

Government agencies

Office of Human Research Protections (OHRP)

The OHRP is the government's main protector of people's safety in clinical trials. The OHRP makes sure that the rules of informed consent, IRBs, and participation of people with special needs are followed. OHRP can stop clinical trials when problems are found. OHRP also teaches research sites and individuals to help them follow current clinical trial standards.

Food and Drug Administration (FDA)

The FDA has the final say about whether a new treatment is approved to be given to

patients. Once phase III clinical trials are completed, the FDA reviews the results of all trials and decides if the new treatment is safe and effective enough to be approved.

The FDA is also involved during the clinical trial. Clinical trials for any new drug, device or treatment must be approved by the FDA before they can begin. The FDA also inspects (audits) sites doing clinical trials, especially if there's reason to think that the site is not following proper procedures. If serious problems are found, the FDA can

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Van Norman GA. Drugs, devices, and the FDA: part 1: an overview of approval processes for drugs. JACC Basic Transl Sci. 2016; 1(3):170-179.

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Being in a Clinical Trial

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criteria.

These criteria are used to make sure that only people who can safely take part in the clinical trial are included.

For cancer clinical trials, the inclusion and exclusion criteria usually have to do with:

- The type of cancer a person has
- The stage (extent) of the cancer
- Previous treatments a person had
- The length of time since a person last had treatment
- Results of certain lab tests
- The medicines a person is taking
- Other medical conditions the person has
- Any previous history of another cancer
- A person's activity level (often called the performance status)

Other factors, such as a person's age or sex, may also be part of the criteria. There are usually other criteria for each study as well.

Informed consent or informed permission

The first thing you will be asked to do is provide written, informed consent. During the informed consent process, the researchers (doctors or nurses) will explain the details of the trial to you and answer your questions and concerns. If you're looking at a study for your child, this process is much the same but may be called informed permission.

You will then be given a written consent form. Consent forms for clinical trials usually include the following:

- The reason for the study (what the researchers hope to find out)
- Who is eligible to take part
- What's known about the new treatment
- The possible risks and benefits of the new treatment
- Other treatments that may be an option for you
- The design of the study (whether it's randomized, double blinded, etc.)
- How many and what types of tests and doctor's visits will be needed
- Who must pay for the costs of the clinical trial (tests, doctor's visits, etc.) and for

research team will decide if symptoms you're having are related to the clinical trial, and if they need to be treated or your treatment needs to be changed.

What if I want to leave the study early?

You will be told many times before you agree to be in a clinical trial that taking part is always voluntary. This is an important point. You (or your child) have the right to stop taking part in the study at any time, for any reason. You'll want to know how quitting the study might affect your health and what other treatment options you have. You should also tell the clinical trials team that you're quitting and why. The clinical trials team may ask to continue to follow up with you for a certain length of time to look for any long-term effects of treatment. This helps find unexpected problems and can make sure you are safe, even though you're no longer part of the clinical trial. Your doctors will still take care of you to the best of their ability.

People stop being part of clinical trials for many reasons. You might quit because it's not working for you. You might leave the trial because of severe side effects. Or you just decide you no longer want to be in it. THIS IS YOUR CHOICE and not a problem.

Also, the clinical trial itself may be ended early if the treatment being studied is proven to work or NOT work as well as the standard treatment. Sometimes, the new treatment is found to have side effects that cannot be managed.

What if I'm not eligible for a clinical trial?

Sometimes, there are ways to get access to treatments that are in late-phase clinical trials but not yet approved by the FDA. These are usually referred to as **expanded access** or compassionate use programs. In recent years the FDA has broadened these programs to allow some patients who urgently need these treatments to be able to get them. For more, see Compassionate Drug Use[4].

Hyperlinks

1. www.cancer.org/cancer/managing-cancer/finding-care.html
2. www.cancer.org/cancer/diagnosis-staging/tests/understanding-your-lab-test-results.html
3. www.cancer.org/cancer/diagnosis-staging/tests.html
4. www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials/compassionate-drug-use.html

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Finding a Clinical Trial

At one time, clinical trials were done only at major medical centers. Many patients had to travel a long way and were treated by doctors they didn't know very well. For some trials, especially with phase I and some phase II studies, this can still be the case. But this isn't always a bad thing. Some people prefer to be treated in major cancer centers because of their experience, reputation, and resources. The hassles of traveling must be weighed against the chance of being helped by the treatment.

Today, patients have more options. This may include staying closer to home during a study or even staying with their own doctors. Your doctor may or may not be involved in clinical trials. If they are, they might have one that is a good fit for you. Whether they have the right study for you is a question worth asking. And know that while clinical trialsNazw0l cewR

There are groups that provide ways to search for clinical trials on their websites. Many of these groups also have people who can help you with your search.

Search results often include a description of each study, factors that people must meet to go into the trial (eligibility), and a contact person. These sites also help you focus your search using factors like your type and stage of cancer, the kind of treatment[1] you're looking for (chemotherapy, immunotherapy, radiation therapy, etc.) and where you live.

General cancer clinical trial listings

There are several websites that give details about clinical trials for all types of cancer. The clinical trials on each of these sites may be a bit different, but most trials will be on all sites. Many of these groups also have a phone number you can call for help with your search. Here are some of the most often used resources.

- National Cancer Institute (NCI) provides an online search tool for cancer clinical trials at https://www.cancer.gov/research/participate/clinical-trials-search[2]. You can ask for help with a search by calling 1-800-4-CANCER (1-800-422-6237).
- Center for Information and Study on Clinical Research Participation (CISCRP) provides an online search tool at ciscrp.org/[3]. You can also get help with searches at 1-877-MED HERO (1-877-633-4376).
- National Institutes of Health (NIH) has a large database of clinical trials at clinicaltrials.gov[4]. Not all the studies listed are cancer clinical trials.
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so making sense of them can be tough. Often, the most important information for patients is the eligibility criteriaand any details known on the new treatment.

Clinical trial lists may not contain all of the eligibility criteria. If you've found a study you think you might qualify for, you should be able to find contact information for someone who can give you a full list of the requirements.

I think I'm eligible. Now what?

Once you've found a clinical trial and think you are eligible for it, deciding if it's the right one for you can still be hard. There may even be more than one trial that looks like an option. It's important to learn as much as you can.

Talk with someone linked to the clinical trial. This could be the clinical or principal investigator (PI) – the person in charge of the study – or a research coordinator. Research coordinators are usually nurses. One of their jobs is to make sure that people understand the trial and meet eligibility criteria before they become part of a study. They also make sure that the study protocol is followed for each patient. The research coordinators often serve as links between study patients and their doctors.

Both PIs and research coordinators should be able to answer your questions about the clinical trial. They can give you answers about the clinical trial, but they probably won't have information about other studies you might be thinking about. What's more, they could be biased (even if they don't mean to be) toward their own study.

Talk to your cancer or primary care doctor about the clinical trials you're looking at. Share the details you have so that your doctor can help you figure out what might be right for you. No doctor knows about every clinical trial being done, but your doctor knows your medical situation best and can probably tell you if the study is worth thinking about. This can take some time, so you might need to make a special appointment.

may give you insight into things you hadn't thought about.

Hyperlinks

1. www.cancer.org/cancer/managing-cancer/treatment-types.html
2. www.cancer.gov/research/participate/clinical-trials-search
3. www.ciscrp.org/
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