

Introduction

This guide will help you to look for a cancer treatment clinical trial that might benefit you. It is not intended to provide medical advice. You, your health care team, and your loved ones are in the best position to decide whether a clinical trial is right for you.

This guide will help you to

- gather the information you need to begin your search for a clinical trial
- identify sources of clinical trial listings
- learn about clinical trials that may be of benefit to you
- ask questions that will help you decide whether or not to participate in a particular trial

A Word About Timing

Many treatment trials will only take patients who have not yet been treated for their condition. Researchers conducting these trials are hoping to find an improved “first-line” treatment option for that type of cancer.

- If you are newly diagnosed with cancer, the time to consider joining a clinical trial is before you’ve had surgery, chemotherapy, radiation, or other forms of treatment (tests to diagnose your cancer are okay). However, don’t delay treatment if waiting could harm you. Talk with your doctor about how quickly you need to make a treatment decision.
- If you have received one or more forms of treatment and are looking for a new treatment option, there also are many clinical trial options for you. You may want to look for trials that are testing a new follow-up treatment that may prevent the return of your cancer. Or if your first treatment failed to work, you may want to look for trials of new “second-line” or even “third-line” treatments.

Before You Start

This section will help you to

- have a better understanding of clinical trials
- gather information you will need in order to locate clinical trials that are appropriate for you

➤ Step 1: Understand Clinical Trials

This guide assumes you already know what clinical trials are and why you might want to join one. If you need to, review your understanding of clinical trials before you continue the steps in this guide.

The Learning About Clinical Trials section of the National Cancer Institute’s Web site (<http://www.cancer.gov/clinicaltrials/learning>) offers a variety of articles to help you understand what cancer clinical trials are, why they are important, and how they work. The articles also describe the different phases of clinical trials and will help you to better focus your search for trials.

➤ Step 2: Talk With Your Doctor

When considering clinical trials, your best starting point is your doctor and other members of your health care team.

Your primary care physician, cancer doctor (oncologist), surgeon, or other health care provider might know of a clinical trial you should consider. He or she can help you determine whether a clinical trial might be a good option.

Note: *In some cases, your doctor may be reluctant to discuss clinical trials as a treatment option for you. Some doctors are unfamiliar with clinical trials, cautious about turning your care over to another medical team, or wary of the extra time that joining the clinical trial might require of them and their staff. If so, you may wish to get a second opinion about your treatment options and clinical trials.*

Remember, you do not always need a referral from

your doctor to join a clinical trial. If you are eligible to join a trial (discussed in Step 3), the final decision is up to you. However, be sure to consider the professional opinions of your doctor. He or she may present very specific reasons why a clinical trial may not be beneficial for you right now.

▶ **Step 3: Complete the Diagnosis Checklist**

Before you begin looking for a clinical trial, you must know certain details about your cancer diagnosis. You will need to compare these details with the eligibility criteria of any trial in which you are interested. Eligibility criteria are the guidelines for who can and cannot participate in a particular study.

To help you gather the details of your diagnosis so you will know which trials you may be eligible to join, complete the Diagnosis Checklist on pp. 10-11. The form asks questions about your diagnosis and provides room to write down answers. Keep this form with you during your search for a clinical trial.

To get the information you need for the form:

- Ask a nurse or social worker at your doctor's office for help. Explain to them that you are interested in looking for a clinical trial that may benefit you and that you need these details before starting to look. They will be able to review your medical records and help you fill out the form.

Searching for a Trial

You have learned what clinical trials are and how they work, talked with your doctor about your interest in clinical trials, and prepared a checklist of key details about your diagnosis. You are now ready to search for clinical trials.

This section will help you to

- find and search trustworthy lists of ongoing clinical trials
- compare your Diagnosis Checklist with a trial's

eligibility criteria, as provided in the trial's description (also called a protocol summary)

- identify those trials that might be good options for you

Note: *It is important to understand the possible biases and limitations of any clinical trials listing. To learn more, see Questions to Ask About a Clinical Trials Web Site (<http://www.cancer.gov/clinicaltrials/finding/questions-about-web-sites>).*

▶ **Step 4: Search the PDQ® Clinical Trials Database**

There are many nonprofit and for-profit resources in the United States that offer lists of cancer clinical trials. Unfortunately, no single list is complete. Clinical trials are run by many different organizations, so it is hard to collect information about all of them in one place.

However, most such resources obtain their lists from the Physician Data Query (PDQ) clinical trials database, maintained by the U.S. National Cancer Institute (NCI).

The NCI is the U.S. government's chief agency for cancer research and is part of the National Institutes of Health. The PDQ clinical trials database contains a list of more than 2,000 cancer clinical trials worldwide.

Important: Get a Copy of the Protocol Summary

Steps 4 and 5 describe where to look for cancer clinical trials. Whichever resource you use, be sure to get a copy of the protocol summary for each trial you are interested in.

What is a protocol? It's the action plan for the trial. The protocol explains what will be done in the trial, how, and why. The protocol should also list the location(s) where the trial will enroll participants.

Both PDQ and ClinicalTrials.gov (Step 4) provide detailed summaries of the official protocols for each trial listed on their Web sites. Other resources (Step 5) may or may not provide protocol summaries.

Note: The U.S. National Library of Medicine maintains a database called *ClinicalTrials.gov* (<http://www.clinicaltrials.gov>) that includes trials for many diseases and conditions, including cancer. The PDQ and *ClinicalTrials.gov* databases contain the same cancer treatment trial listings. The main difference is in how information is searched and displayed. You may prefer one way over another.

How to Search PDQ

1. Search PDQ by telephone.

Make a free telephone call — in English or Spanish — within the United States to the National Cancer Institute’s Cancer Information Service (CIS) at 1-800-4-CANCER (1-800-422-6237). All calls to the CIS are strictly confidential.

- When you call the CIS, be ready with the details of your Diagnosis Checklist from Step 3.
- The CIS is staffed with understanding and knowledgeable information specialists who will search PDQ for you. They can send you the search results and protocol summaries by e-mail, fax, or regular mail. The CIS can also provide you with reliable information about your type of cancer and the current standard therapy for treating it.

2. Search PDQ through the NCI Web site.

You can look for trials yourself using a PDQ search form on the NCI Web site. Remember to print out the protocol summaries for each trial you may be interested in.

- The basic search form (<http://www.cancer.gov/clinicaltrials/>) allows you to search by type of cancer, stage or subtype of cancer, and location of trial (ZIP code).
- The advanced search form (<http://www.cancer.gov/search/searchclinicaltrialsadvanced.aspx>) lets you create your search using more detailed information, such as the hospital or institution involved, type of treatment, and phase of trial.
- If you would like help searching PDQ while you’re online, consider using LiveHelp (<https://cissecure.nci.nih.gov/livehelp/welcome.asp>). Through LiveHelp, you can communicate

confidentially and in real time with a CIS information specialist from the National Cancer Institute. The service is available Monday through Friday from 9:00 a.m. to 10:00 p.m. ET.

▶ Step 5: Search Other Resources

While PDQ has the most complete listing of cancer trials, you might want to check a few other resources, as well. Why? Because

- some may include a few trials not found in the federal databases
- you may prefer their way of assisting you in your search

The other resources discussed in this section are

- TrialCheck®
- Third-Party Clinical Trial Web Sites
- Industry-Sponsored Cancer Trials
- Cancer Advocacy Groups
- Fee-Based Search Services

Note: Links to external Web sites are provided for convenience and informational purposes only. The inclusion of these links does not constitute an endorsement by the National Cancer Institute. See the full *Disclaimer of Endorsement and Liability* policy for the NCI Web site (<http://www.cancer.gov/policies>).

TrialCheck

TrialCheck is operated and maintained by the Coalition of National Cancer Cooperative Groups (CNCCG). The CNCCG is made up of groups of doctors and other health professionals that carry out many of the large cancer clinical trials in the United States funded by the National Cancer Institute.

TrialCheck includes fewer trials than either PDQ or *ClinicalTrials.gov* - the two government databases described in Step 4.

However, because TrialCheck helps you search its list through an online form that “interviews” you about your cancer and the kind of treatment(s) you have received, you might prefer this kind of service.

How to search TrialCheck

- The Frequently Asked Questions (FAQs) page on the TrialCheck Web site (<http://www.trialcheck.org/cancertrialshelp/>) provides helpful information about how to use TrialCheck.

Third-Party Clinical Trial Web Sites

There are a number of clinical trial Web sites that are not operated by funders, sponsors, or the organizations carrying out the trials. Some of these Web sites are operated by private companies — these may be funded through fees that industry sponsors pay to have their trials listed or according to how many participants the Web site refers to them.

Keep the following points in mind:

- Most third-party clinical trials Web sites list or link to trials from PDQ or ClinicalTrials.gov.
- They may include a few more trials than you'll find in the federal databases, but they may also include fewer.
- Unlike the federal databases, these sites may not regularly update their content or links.
- Unlike the federal databases, these sites might require you to register, either to search for trials or to obtain contact information about the trials that interest you.

Links to several third-party Web sites are listed below. Clicking on the links will help you learn more about the sites and what they have to offer in addition to their clinical trial listings.

- Acurian (<http://www.acurian.com/>)
- Cancer411 (<http://www.cancer411.com>)
- CancerConsultants (<http://www.patient.cancerconsultants.com>)
- CenterWatch (<http://www.centerwatch.com>)
- ClinicalTrialsSearch.org (<http://www.clinicaltrialssearch.org>)
- EmergingMed (<http://www.emergingmed.com>)
- Veritas Medicine (<http://www.veritasmedicine.com>)

Industry-Sponsored Cancer Trials

Pharmaceutical and biotechnology companies sponsor many of the cancer clinical trials being

carried out in the United States. Some of these trials are listed in the federal databases (PDQ and ClinicalTrials.gov) but many are not.

Federal law requires that U.S. researchers submit to ClinicalTrials.gov all phase II, III, and IV trials of therapies for serious or life-threatening illnesses (including cancer) conducted as part of the approval process overseen by the U.S. Food and Drug Administration. However, this law is difficult to enforce and for business reasons, drug companies may prefer to keep details about their clinical trials from the public.

How to search for industry-sponsored trials

- If you are aware of an experimental cancer treatment and know the company that manufactures it, search the Internet to find the Web site of the company. Find the company's customer service telephone number. When you call, ask to speak to the company's clinical trials department. Tell them you are looking for a trial that you might be eligible to join.

Cancer Advocacy Groups

Cancer advocacy groups work on behalf of people diagnosed with cancer and their loved ones. They provide education, support, financial assistance, and advocacy to help patients and families who are dealing with cancer. These organizations recognize that clinical trials are important to the cancer treatment process and, thus, work to educate and empower people to find information and access to treatment.

Because they work hard to know about the latest research advances in cancer treatment, these groups will sometimes have information about certain key government-sponsored trials, as well as some potentially significant trials sponsored by pharmaceutical companies or cancer care centers.

How to search for trials through a cancer advocacy group

- Contact the advocacy group for the type of cancer you are interested in and ask what they can tell you about ongoing clinical trials. The nonprofit Marti Nelson Cancer Foundation maintains a partial list

of such groups (<http://www.canceractionnow.org/living/cancerresources.php#disease>) on its CancerActionNow Web site.

Fee-Based Private Search Services

A number of private services will, for a fee, locate clinical trials for you. While having someone search for you may ease your stress, it is important to keep in mind that several of the resources mentioned earlier in this guide provide elements of this kind of service for free. Also, be sure to ask the following questions:

- What list or lists of clinical trials does the service search? Are those lists likely to provide you with an unbiased and largely complete source of options?
- Does the service receive any money for directing patients to certain trials or for including certain trials in their list?

Step 6: Make a List of Potential Trials

At this point you have created a Diagnosis Checklist, identified one or more trials you might be interested in, and obtained a protocol summary for each one.

This section will help you to

- take a closer look at the protocol summaries
- narrow your list to those trials you would like to get more information about

Now it's time to take a closer look at the protocol summaries you have obtained for the trials you're interested in. You should remove from your list those trials you aren't actually able to join and come up with one or more top possibilities.

What follows are some key questions to consider about each trial. However, don't worry if you cannot answer all of these questions just yet. The idea is to narrow the list if you can, but don't give up on one that you're not sure of.

Note: Ideally, you should consult your doctor during this process, especially if you find the protocol

summaries difficult to understand. But you can probably do Step 6 yourself if the protocol summary is relatively complete and easy to understand.

- **Trial objective.** What is the main purpose of the trial? Is it to improve your chances of a cure? To slow the rate at which your cancer may grow or return? To lessen the severity of treatment side effects? To establish whether a new treatment is safe and well tolerated? Read this information carefully to learn whether the trial's main objective matches your goals for treatment.
- **Eligibility criteria.** Do your diagnosis and current overall state of health match the eligibility criteria (sometimes referred to as enrollment or entry criteria)? This may tell you whether you could qualify for the trial. If you're not sure, keep the trial on your list for now.
- **Trial location.** Is the location of the clinical trial manageable for you? Some trials are available at more than one site. Look carefully at how often you will need to receive treatment during the course of the trial, and decide how far and how often you are willing to travel. You will also need to ask if the sponsoring organization will provide for some or all of your travel expenses.
- **Study duration.** How long will the study run? Not all protocol summaries list this information. If they do, consider the time commitment and whether it will work for you and your family.

If after considering these questions you are still interested in one or more of the clinical trials you have found, then you are ready for Step 7.

After Finding a Trial

Now that you have found one or more clinical trials for which you think you are eligible and which may be a good treatment option for you, it is time to make a telephone call to each trial's contact person so you can ask a few more crucial questions. Then you will be ready to make a final treatment decision.

➤ Step 7: Contact the Clinical Trial Team

There are several ways to contact the Clinical Trial Team.

- **Contact the trial team directly.** The protocol summary should include the name and telephone number of someone you can contact for more information. You do not need to talk to the lead researcher (called the “protocol chair” or “principal investigator”) at this time, even if that is the name that is included with the telephone number. Instead, call the number and ask to speak with the “trial coordinator,” the “referral coordinator,” or the “protocol assistant.” This person can answer questions from potential patients and their doctors. It is also this person’s job to determine whether you are likely to be eligible to join the trial. (A final determination would be made only after you had gone in for a first appointment.)
- **Ask your doctor or other health care team member to contact the trial team for you.** Because the clinical trial coordinator will ask questions related to your diagnosis, you may want to ask your doctor or someone else on your health care team to contact the clinical trial team for you.
- **The trial team may contact you.** If you have used some of the third-party Web sites and identified trials that interest you, you may have provided your name, phone number, and e-mail address so that the clinical trial team can contact you.

You will need to refer to your Diagnosis Checklist (Step 3) during the conversation, so keep that handy.

What’s more, it will be helpful if you can talk about your diagnosis in a manner that is brief and to the point. Before you make the call, rehearse with a family member or friend how you will present the key details of your diagnosis. This will make you more comfortable when you are talking with the clinical trial coordinator and will enable you to answer his or her questions smoothly.

➤ Step 8: Ask Questions About the Trial

Whether you or someone from your health care team calls the clinical trial coordinator, this is the time to get answers to questions that will help you decide whether or not to join this particular clinical trial.

1. Is the trial still open? On occasion, clinical trial listings will be out-of-date and will include trials that have actually closed to further enrollment.

2. Am I eligible for this trial? The trial coordinator will ask you many, if not all, of the questions listed on your Diagnosis Checklist (Step 3). This is the time to confirm that you are indeed a candidate for this trial, although a final decision will likely await your first appointment with the clinical trial team (Step 10).

3. Why do researchers think the new treatment might be effective? Results from earlier clinical trials will highlight the potential effectiveness of the treatment you may receive. The strength of the earlier evidence may influence your decision. You or someone who knows how to read the medical literature may also want to use a Web-based service such as PubMed (<http://www.pubmed.org>) to explore any previously published evidence related to the trial you’re interested in.

4. What are the risks and benefits associated with the treatments I may receive? Every treatment has risks. Be sure you understand what risks and side-effects are associated with any of the treatments you might receive as a participant in this trial. Likewise, ask for a detailed description of how the treatments may benefit you.

5. Who will monitor my care and safety? Primary responsibility for the care and safety of patients in a cancer clinical trial rests with the clinical trial health care team. In addition, clinical trials are governed by safety and ethical regulations set by the federal government and the institution or organization sponsoring and carrying out the trial, including a group called the Institutional Review Board (IRB). The trial coordinator will be able to give you more information. You can also see *Protecting Participants in Clinical Trials* (<http://www.cancer.gov/clinicaltrials/digestpage/protecting-participants>).

6. May I get a copy of the protocol document? In some cases, the trial coordinator may be allowed to release the full, detailed protocol document to you. However, the protocol summary and the informed consent document will probably answer most of your questions about the trial’s design and intention.

7. May I get a copy of the informed consent document? The U.S. Food and Drug Administration requires that potential participants receive complete

information about the study. This process is known as “informed consent” and must be in writing. It may be helpful to see a copy of this document before you decide whether or not to join the trial. For more information about informed consent, see *A Guide to Understanding Informed Consent* (<http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide>).

8. Is there a chance I will receive a placebo? Placebos are rarely used in cancer treatment trials, but be sure you understand what possible treatments you may or may not receive for any trial you are thinking of joining.

9. Is the trial randomized? In a randomized clinical trial, participants are assigned, by chance, to separate groups or “arms.” Each arm receives a different treatment, and the results are compared. In a randomized trial, you may or may not receive the new treatment. See *What Is Randomization?* (<http://www.cancer.gov/clinicaltrials/learning/what-is-randomization>).

10. What is the treatment dose and schedule in each arm of the trial? You will want to consider this when you are discussing your various treatment options with your health care team. Does the dose seem reasonable? Is the treatment schedule manageable for you?

11. What costs will I be responsible for? In many cases, the research costs are paid by the group sponsoring the trial. Research costs include the treatments under study and any test performed purely for research purposes. However, you or your insurance plan would be responsible for paying “routine patient care costs.” These are the costs of medical care (e.g., doctor visits, hospital stays, x-rays) that you would receive whether or not you were in a clinical trial. Some insurance plans don’t cover these costs once you join a trial. Consult your health plan, if you have one, or go to *States That Require Health Plans to Cover Patient Care Costs in Clinical Trials* (<http://www.cancer.gov/clinicaltrials/learning/laws-about-clinical-trial-costs>) to see if your plan must provide such coverage. You may also wish to refer to *Clinical Trials and Insurance Coverage — A Resource Guide* (<http://www.cancer.gov/clinicaltrials/learning/insurance-coverage>).

12. If I have to travel, who will pay for travel and lodging? Some trials may pay for your travel and lodging expenses. Otherwise, you will be responsible for these costs.

13. Will participation in this trial require more time than if I had elected to receive standard care? Will participation require a hospital stay? Understanding how much time is involved may influence your decision and help you make plans.

14. How will participating in the clinical trial affect my everyday life? A cancer diagnosis can be very disrupting to the routine of everyday life. Many patients seek to keep those routines intact as they deal with their diagnosis and treatment. This information will be useful in evaluating any additional help you may need at home.

➤ **Step 9: Discuss Your Options With Your Doctor**

To make a final decision, you will want to know the possible risks and benefits of all the various treatment options open to you. You may decide that joining a trial for which you are eligible is your best option, or you may decide not to join a trial. It is your choice.

For further guidance, see *Participating in a Trial: Questions to Ask Your Doctor* (<http://www.cancer.gov/clinicaltrials/learning/questions-to-ask-about-participating>).

➤ **Step 10: If You Want to Join a Trial, Schedule an Appointment**

If you decide to participate in a clinical trial for which you are eligible, schedule an appointment with the trial coordinator you spoke to during Step 8.

You might also want your doctor to contact the study’s principal investigator to further discuss your medical history and overall current state of your health. The principal investigator’s name should be listed in the protocol summary.

Your doctor might disagree with your decision to participate in a clinical trial. If so, be sure you understand his or her concerns. You also may wish to seek a second opinion about your treatment options at this time. Ultimately, it is up to you to decide what treatment is in your best interest.

Diagnosis Checklist

Fill out this checklist before you start looking for a clinical trial. The checklist will help you know which clinical trials you are eligible to join. See Step 3 (p.3) for details on how to obtain the information you need for the checklist.

1. What kind of cancer do you have?

Write down the full medical name.

2. Where did the cancer first start?

Many cancers spread to the bones, liver, or elsewhere. However, the type of cancer you have is determined by where it first showed up. For example, breast cancer that spreads to the bone is still breast cancer.

3. What is the cancer's cell type?

This information will be in your pathology report.

4. If there's a solid tumor, what size is it?

5. If there is a solid tumor, where is it located?

If the tumor has spread, list all locations.

6. What stage is the cancer?

The stage describes how far it has spread from the original site to other parts of the body. There are different staging systems for different cancers.

7. Have you had cancer before, different than the one you have now? If so, answer questions 1-6 for the other cancer, as well.

8. What is your current performance status?

An assessment from your doctor indicating how well you are able to perform ordinary tasks and carry out daily activities.

9. If you have not yet had any treatment for cancer, what treatment(s) have been recommended to you?

10. If you have had treatment for cancer, please list (for example, type of surgery; chemotherapy, immunotherapy, or radiation).

11. Bone marrow function (blood tests that check whether your blood count is normal):

a) White blood cell count:

b) Platelet count:

c) Hemoglobin/hematocrit:

12. Liver function (blood tests that check whether your liver function is normal):

a) Bilirubin:

b) Transaminases:

13. Renal function (blood test that checks whether your kidney function is normal):

Serum creatinine:

For More Information

Visit the NCI Web site at
<http://www.cancer.gov/clinicaltrials>.

or call the NCI's Cancer Information Service
at 1-800-4-CANCER

Who Produced This Guide?

Representatives from several organizations worked together to produce this guide.

- The U.S. National Cancer Institute (<http://www.cancer.gov>) — The federal government’s chief cancer research agency and part of the U.S. National Institutes of Health
- The U.S. Food and Drug Administration (<http://www.fda.gov>) — the division of the U.S. Department of Health and Human Services charged with ensuring the safety and effectiveness of new drugs and other products
- The Summit Series on Cancer Clinical Trials (<http://www.cancersummit.org>), sponsored by a variety of nonprofit groups including patient advocates, physicians, nurses, and others involved in the U.S. cancer clinical trial system