PATIENT RESOURCE

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12th Edition

CANCER CLINICAL TRIALS

RESEARCH FUELS TREATMENT ADVANCES

MULTIPLE MYELOMA SURVIVOR DEFIES ODDS WITH CLINICAL TRIALS

See page 6

FLIP OVER! To read CANCER GUIDE

CANOVA
THE CANOVA STUDY

Canova Study: A Study in patients with relapsed or refractory multiple myeloma who are refractory to lenalidomide and have received a proteasome inhibitor.

MULTIPLE MYELOMA RESEARCH STUDY

Do you or someone you know have **Relapsed** or **Refractory Multiple Myeloma**?

This research study is evaluating the safety and effectiveness of an investigational medication in combination with standard treatment and versus standard treatment for patients with Relapsed or Refractory Multiple Myeloma.

PATIENTS MUST MEET THE FOLLOWING CRITERIA:

- 18 years of age or older
- Diagnosed with Relapsed or Refractory Multiple Myeloma with measurable disease
- Must test positive for the t(11;14) translocation biomarker
- Study-specific treatment requirements:
  - Must have evidence of disease progression on or within 60 days of the last dose of the most recent treatment regimen
  - Must have previously received at least two lines of therapy, including being relapsed/refractory to lenalidomide, an immunomodulatory agent (IMiD) and exposed to a proteasome inhibitor (PI)
  - Must not have previously received pomalidomide or the investigational medication
- Other criteria apply

For more information, ask your doctor about the CANOVA Study or visit www.**MMCanovaTrial.com** (NCT: 03539744) to see if you qualify.

12th Edition

CANCER CLINICAL TRIALS

IN THIS GUIDE

We take an active role. We took advantage of six clinical trials, and we partner with our medical team.

~ ***Jim Bond,*** *clinical trials participant & multiple myeloma survivor, page 6*

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Research leads the way for more promise in cancer treatment

The COVID-19 pandemic put clinical trials in the spotlight as researchers worked to develop a vaccine. Many people were not familiar with clinical trials, but they are not new. They have been used for hundreds of years, and the research advances made as a result are integral to testing and approving new cancer treatment strategies.

DEFINING CANCER CLINICAL TRIALS

A clinical trial is a research study that tests a new medical approach. Most cancer treatments used today were once therapies or procedures that were developed, tested and evaluated through the clinical trials process to gain approval from the U.S. Food and Drug Administration (FDA).

Many types of cancer clinical trials exist. Some evaluate new methods for improving different areas of cancer care, including disease prevention, patient screening, diagnostic tools and procedures, genetic risk factors, and lifestyle or behavioral changes that may improve health and/or quality of life (having fewer or more manageable side effects, for example). This includes testing drugs and non-medication therapies, such as radiation therapy, surgery, medical devices and other interventions. Trials may also evaluate patient-reported outcomes, which are important to improving the quality of patient care.

THE RISE OF TELEHEALTH

When the country shut down in spring 2020, many cancer clinical trials were halted for patient safety. Scientists and researchers had to find new, efficient and safe ways of conducting clinical trials. Telehealth was key to continuing them during the pandemic, and many researchers think these changes are here to stay.

Telehealth is the delivery of health care from a distance using electronic information and technology such as computers, cameras, video conferencing, the internet, satellite and wireless communications. You may also hear a telehealth appointment referred to as a "virtual appointment."

The use of telehealth for clinical trials has offered patients many advantages, including the following:

- Allowing more patients to participate in trials from even greater distances.
- The convenience of remaining at home.
- Reducing travel for people who live far from the medical office, which eliminates transportation costs.
- Helping limit potential exposure to infections in clinics and hospitals.
- Offering an easy way to report symptoms or complications between follow-up visits.
- Allowing caregivers and family members to ask questions during virtual visits.
- Reducing disruption to a patient's daily life.
- Giving participants the ability to sign the Informed Consent form electronically, avoiding a special trip into a medical facility.

The conveniences of telehealth have brought new possibilities to cancer clinical trials and their participants. These include making trials more flexible, faster, simpler, less expensive and more equitable. Other benefits to participants include the following:

- Investigational drugs may be mailed overnight.
- Wearable technologies will help doctors remotely monitor blood pressure and temperature information, which provides valuable input to the principal investigator of the trial.
- Pharmacists may be more directly involved with clinical trial participants.
- The increased use of digital tools, such as mobile apps, patient portals and electronic health records, simplifies and collects information.
- Patients have more access to specialists including dietitians, psychologists and other health professionals.
- There is greater potential for more volunteers to participate in clinical trials because they will not have to be located near the center.

Other changes and conveniences are likely to be seen as clinical trials continue to evolve. These offer clinical trial volunteers fewer barriers to participate and make joining one less disruptive to your life.

If you are interested in joining a clinical trial, talk to your doctor and discuss all of the options available to you. Use the information in this guide to educate yourself about trials. ■

Understanding the Four Phases of Clinical Trials

Clinical trials are traditionally designed in four phases, and each phase provides the building blocks of knowledge for the next phase. This approach allows researchers to ask and answer questions in a way that produces the most reliable information and provides the most protection to trial participants. The process also ensures that only treatments that have been rigorously studied are approved for the public.

The FDA has shortened its approvals for new therapies. Recently, based on successes of other trials, researchers have begun investigating and conducting seamless trials that begin in earlier phases. Today, the FDA considers approvals at any phase of research, including as early as Phase I trials, and approves therapies before many other countries' organizations. These advances give patients access to lifesaving treatments sooner.

Phase I	Phase II	Phase III	Phase IV
Phase I evaluates a new drug (or other type of treatment) to see if it is safe for use in people. The goal is to determine how the drug should be given, how often and at what dosage to be most effective for killing diseased cells while causing the fewest side effects.	Phase II determines how well a treatment works and how safe it is in a greater number of patients.	Phase III compares the new treatment with the current standard of care to see if it is more effective or has fewer side effects.	Phase IV tests a drug that has already been FDA-approved for the market to gather more information about its effect in different populations and learn about long-term side effects.

Be an active participant in your treatment plan

Looking for a clinical trial is a great way to be involved in your own care. Once you let your medical team know you are open to participating, they will use their resources to find available trials while you search online websites. Get started with the list of clinical trial sites on the right. Ask your friends and family to help. Depending on your diagnosis, there could be many to explore.

GETTING STARTED

Gather your exact diagnosis, pathology report and details of your previous cancer treatments. To customize your search, enter details, such as age and location. If you prefer a clinical trial close to home, enter your home address. Expand the miles surrounding your home if you are willing and able to travel for treatment.

Refine your search by adding a treatment type or genetic mutation. You can also add a National Clinical Trial identifier, which is a unique eight-digit code preceded by "NCT" that is assigned to each trial.

READING YOUR SEARCH RESULTS

You will see a list of trials that match your criteria. Details include recruitment status, which indicates whether the trial is actively seeking patients, not yet recruiting or otherwise inactive. Be aware that the status will change, so check often for updates.

The study description explains the purpose of the clinical trial and the treatment being studied. This section is usually written for health care providers, so it may be difficult to understand. If it is, print out the information to discuss with your doctor.

Also included are the criteria you must meet to be eligible for the trial, such as the stage of disease, sites of metastasis, overall health requirements and previous treatments.

Contact information for the clinical trial investigators, staff or sponsors may be listed. These are resources who may be able to provide more details and answer questions about the study.

The sponsor (the entity responsible for the clinical trial) is listed. It may be a pharmaceutical or biotechnology company, a university, the National Cancer Institute or others. ■

➥ Clinical Trial Resources

Cancer Support Community:
www.cancersupportcommunity.org/find-clinical-trial

Cancer Support Community Hotline:
888-793-9355

Center for Information & Study on Clinical Research Participation:
www.searchclinicaltrials.org

ClinicalTrials.gov:
www.clinicaltrials.gov

Lazarex Cancer Foundation:
www.lazarex.org, 877-866-9523

National Cancer Institute:
www.cancer.gov/clinicaltrials

NCI Cancer Information Service:
800-422-6237

WCG CenterWatch:
www.centerwatch.com, 866-219-3440

Dispelling the common myths of clinical trials

The internet is often the first place people go to research their type of cancer. Though it does contain a lot of information, not all of it is helpful and some may not even be true. It can be challenging to know where to go and whom to trust. Myths can easily influence your decision and prevent you from exploring this potential treatment option. Becoming an educated patient empowers you to get the facts and make the best choices for you.

The first place to ask about cancer clinical trial information should be your doctor and health care team. If you want to search for trials on your own, see *Searching for a Clinical Trial*, above.

When you know the facts, you'll be more informed and confident as you talk with your doctor and loved ones about joining a clinical trial.

Only you can decide whether to be involved in a clinical trial. Do your research, consult with your doctor, and talk to the medical team that will manage your care during the clinical trial. Do not let misinformation prevent you from getting the best available information and care.

In this article, we bust some of the most common myths surrounding clinical trials to provide the information you need to feel comfortable discussing this potential treatment option with your doctor. ■

Following are some common myths about cancer clinical trials and the facts that dispel them.

MYTH: ***Drug therapies used in cancer clinical trials are unapproved and therefore unsafe.***
FACT: Trials are designed with strict safety measures in place that were established and are enforced by the U.S. Food and Drug Administration. While many trials are focused on the development of new treatments, the majority of cancer clinical trials include treatments that are already approved, sometimes alone and sometimes in combination with new therapies.

MYTH: ***I can't participate if I don't live near a city with a large cancer center.***
FACT: Clinical trials take place in nationally known cancer centers in major cities, in university medical centers, regional hospitals and even oncologists' offices. And, thanks to advances in technology, many trials today are using telehealth so you don't have to travel for appointments or sign the Informed Consent form in person.

MYTH: ***Once I start the trial, I can't change my mind.***
FACT: Participation is always voluntary, even after the trial has started. You can withdraw at any time and for any reason.

MYTH: ***I can only join a trial if I have no other treatment options.***
FACT: It is common for many people to feel this way, but trials today are open to patients at every stage. Depending on the diagnosis, a clinical trial may be considered as a first-line treatment.

MYTH: ***I'm afraid I'll receive a placebo instead of treatment.***
FACT: Placebos are rarely used in cancer clinical trials, but combination studies frequently use a placebo in the control arm and are done with the full knowledge of the participants. When placebos are used, they are used in combination with the current standard of care. Trials divide participants into separate groups that compare different treatments. At the time of the trial, it is not known which treatment is best.

Caregivers provide crucial support during a clinical trial

Your role as a caregiver may not be new. You may be accustomed to helping your loved one with many important tasks, from attending medical appointments and managing medications to preparing meals and communicating with the health care team, family and friends. But, if a treatment clinical trial is the next step for your loved one, you should know that some of your responsibilities will take on increased importance.

The reason your responsibilities will be different is because the goal of the trial is to measure the effectiveness of the experimental treatment. Very specific protocols are put in place, and every participant in the clinical trial must follow them to ensure the scientific data is most helpful. You will be an integral part in ensuring your loved one adheres to the protocols and reporting the required data.

At first these new responsibilities may seem overwhelming, but they are also exciting. Along with participating in a trial that hopefully helps your loved one feel better or even be cured, you both are making a valuable contribution to the future of cancer care.

Every clinical trial is different, but here are key things to know and ways you may help.

Listen and learn together. Facing cancer is scary, and the unknowns associated with a clinical trial may add questions. Use the resources in this guide and those from your loved one's medical team and clinical trial team to learn more about the clinical trial process. Once your loved one selects a trial, read the Informed Consent form thoroughly. It provides details about the specific trial, including the goal of the trial, the number of appointments, the therapy being used and more. The more you know, the more comfortable you both will be moving forward.

Get the OK to receive medical information. One of the first things to do is make sure you are authorized to communicate with the clinical trial team, access medical information, renew prescriptions and more. You are likely set up to do this with your loved one's health care team, but it is wise to check with the clinical trial team in case any additional forms are required. If you are unsure about the forms you may need to sign, ask a member of the clinical trial team.

Transport to and from appointments. Often, trials require more appointments than a typical treatment plan. It is necessary that your loved one goes to every scheduled appointment, from screening through the end of the trial. Make sure your schedule at work or at other commitments will allow for you to take your loved one to and from each appointment.

Ask if telehealth appointments are available. Using computers, phones, video conferencing and the internet, telehealth allows you to communicate with your clinical trial team without having to travel to the clinical trial location. The stress and effort involved with getting to and from frequent appointments could be alleviated if some of those appointments could be done by this convenient option.

Collecting data. The timely and detailed reporting of symptoms, side effects and other key indicators is crucial. To ensure you understand the information to track and why you are tracking it, plan to attend all appointments with your loved one. Information to collect may involve medication schedules, adverse reactions and data captured from monitoring devices. The trial depends on the quality and quantity of the data collected.

Ask about remote monitoring options. Sometimes data can be collected electronically using a phone, tablet or other device. This option could offer a convenient alternative to traveling to an in-person appointment.

Write down your questions. You may have questions that are not part of the "required" information that you are asked to report. At the beginning of the clinical trial, ask the trial team whom to contact with your questions and when it is appropriate to reach out. It may be the principal investigator or another member of the study team. Also ask about the preferred contact method, such as mail, health care portal, telephone call or messaging.

Plan for respite care. These new tasks must be performed regularly for as long as the trial lasts. That can add a great deal to your duties, especially if you work, have children, care for other relatives or have other responsibilities. For your mental and physical well-being, you should plan for others to help you with certain things.

Before you shrug off this advice, keep this in mind: You could become worn down or find it difficult to keep up with the requirements of the clinical trial. As a result, your loved one may not get the intended treatment, and the trial itself will suffer because the protocols will not be followed. In extreme cases, your loved one may be asked to leave the trial. Ask the clinical trial team if they offer any participant support services, such as transportation.

Take care of yourself. You will be a more effective caregiver if you feel emotionally and physically healthy. Keep up with your medical appointments, social relationships, hobbies and exercise plan. Share your feelings with friends, a therapist or spiritual leader. Consider connecting with other caregivers of people in clinical trials. ■

M15-538

Multiple Myeloma
Research Study

This research study is evaluating the safety and effectiveness of an investigational medication in combination with standard treatment for patients with Relapsed or Refractory Multiple Myeloma.

Do you or someone you know have Relapsed or Refractory Multiple Myeloma?

Patients must meet the following criteria:

- 18 years of age or older
- Diagnosed with Relapsed or Refractory Multiple Myeloma with measurable disease
- Study-specific treatment requirements:
  - Must have had at least one prior line of therapy
  - Have not received treatment with carfilzomib, dexamethasone, or BCL-2 inhibitors
- Other criteria apply

For more information, ask your doctor about this study or visit **www.MM538Trial.com**

Today, Jim and his wife, Kathleen, share their story of setbacks, struggles and joy. They strongly believe every myeloma case is different and hope their experiences will encourage others facing the disease.

Strong-willed survivor shares his story to inspire others

In 1992, I was 43 and happily married with two college-aged sons when results from a physical showed a slight protein increase in my urine. I followed up with blood work, X-rays and a bone marrow biopsy (spoiler alert — this was the first of 38 bone marrow biopsies), after which my doctor told me I had Stage III multiple myeloma.

My ribs were broken. I also had bone damage in my spine and lesions on my skull. He said if I did nothing, I had a few months to live. If I did all I could, two to three years. My wife, Kathleen, and I were numb. We'd never even heard of multiple myeloma.

He told us about an oncologist at another hospital who had more experience with multiple myeloma than he did. He believed I'd have a better shot with him, and he'd help me get in with him. I learned then just how compassionate oncologists can be.

We met with the oncologist. We liked him, so we mapped out a plan. We confirmed the plan with myeloma oncologists who were publishing articles at the time. That gave us confidence.

After chemotherapy and an autologous stem cell transplant, I went into remission for five years. I knew it would come back (it always does). When it did, I asked my doctor if I could have another autologous transplant. He hesitated because I'd had full body radiation but agreed. That bought me a couple of years.

In late 2001, I needed more treatment. My older sister was a bone marrow match for me, and I had my first allogeneic transplant. The disease came back. We were disappointed but not surprised.

In early 2002, I couldn't eat, I ran high fevers and my kidneys were shutting down. We'd heard about a clinical trial at a different hospital, but there were no openings. Another doctor gave me a list of hospitals to try. I left messages with all of them. A doctor associated with a trial called. He asked how soon I could get there and if I was willing to relocate for nine months. That he thought I could live that long was incredible. I packed enough for nine months and noticed Kathleen packed for what looked like a weekend. I had a 104-degree fever and was a little foggy, so I didn't think much about it. When my sister dropped us at the airport, she was very emotional. Again, I didn't dwell on it.

Our first night there, Kathleen called the doctor because she didn't think I'd make it through the night. He said, "Your husband is the seventh person in our trial. That makes his trial number 007. I think that's good karma for your husband, Mrs. Bond." And it was.

A few months later, I was in complete remission. It then dawned on me that Kathleen had only packed for a few days because she didn't think I'd make it, and when my sister said goodbye at the airport, she was saying goodbye forever.

Kathleen decided to develop a cycling fundraising event. I told her it was a great idea with just one problem. We didn't cycle. To her, that was a minor detail. She launched the first annual Pan Ohio Hope Ride (POHR.org), a 328-mile bike ride over four days that benefits the ACS Hope Lodge, which provides free lodging for cancer patients and their families while they are undergoing treatment. I bought a bike, trained and rode the entire POHR.

In September 2012, I had my 32nd bone marrow biopsy. I had treatment-related leukemia and needed an allogeneic stem cell transplant. My body identified my sister's cells as mine already, so we found a match but the transplant board had to approve it. I was 64, and with my history, they voted no until they learned I'd just finished the POHR two months earlier. They took a chance on my physical and mental strength. I had the transplant that October and was declared in remission in December.

Kathleen has been by my side every step of the way. We take an active role in our situation. We took advantage of six clinical trials, and we partner with our medical team.

We get the most satisfaction out of helping others, which is why I wrote "The Man in the Arena: Surviving Multiple Myeloma since 1992." I hope it encourages them to not give up. Also, 100 percent of the profits go to charities that support multiple myeloma patients.

To promote the book, Kathleen and I have talked to dozens of patient support groups and organizations around the globe. We always make it clear that everyone's experience is different, but we share our story so they can hear how someone with the same diagnosis has lived a long, full life.

One of our favorite stories to share is the 8 p.m. rule, and it can really apply to any situation — cancer-related or not. After 8 p.m., no cancer or medical talk is allowed in our house. We relax, enjoy the evening and get a good night's sleep. It used to be a 9 p.m. rule, but we're a little older now. Kathleen swears that if it ever gets to be a 7 p.m. rule, we won't tell anyone!

It's difficult to know you have an incurable disease, but you can learn to manage your way through it. I hope we are proof there are still memories to be made. We recently celebrated our 50th wedding anniversary.

The book is available on Amazon, and I'm always willing to be a source of emotional support to anyone with multiple myeloma (jim.bond48@gmail.com). ■

Protecting participants is the number one priority

One major concern people may have about joining a clinical trial is whether it is safe. It should be reassuring to know that multiple guidelines and regulations are followed to ensure that all clinical trial participants are protected throughout the process. This is done through several levels of safeguards and a set of rules called a protocol.

The protocol defines the trial's eligibility criteria, specifies the tests and procedures, describes the medications and dosages, and establishes the duration of the study. Before the study begins, a scientific review panel evaluates the protocol carefully to make sure the trial is based on sound science. All participating clinics, hospitals, universities, cancer centers and medical offices, regardless of their size or location, must follow the same protocol.

SAFETY GUIDELINE PROVIDERS

Protecting a patient's safety is the number one priority in clinical trials and is overseen by three main groups. Each manages different aspects of the trials.

The U.S. Food and Drug Administration (FDA) is responsible for the safety, efficacy and security of drugs and has regulated them since the 1970s. It monitors several steps in the drug development process, which requires extensive research and numerous applications before and after clinical testing. The FDA also works closely with pharmaceutical companies to ensure the integrity of new treatments and medications.

Institutional Review Boards (IRBs) review each clinical trial's protocols before the study begins and monitor the trial's ongoing progress from beginning to end. Members are in charge of reducing the risk of harm when compared with possible benefits to participants. An IRB may consist of scientists, doctors, nurses, social workers, chaplains, patient advocates and other health care or community professionals.

Data and Safety Monitoring Boards (DSMBs) review the progress of a clinical trial while monitoring the participants. They also review data on the effectiveness of the trial interventions. Each trial has only one DSMB, and it is usually composed of doctors, statisticians and others who are independent of the people, organizations and institutions that are sponsoring, organizing and conducting the clinical trial. Members are experts in clinical research and clinical trials, and they can stop a trial early if safety concerns develop.

In addition to safety oversight from these groups, the government passed the National Research Act in 1974, which ultimately led to the creation of three basic ethical guidelines for clinical trials:

1. **Respect for people** — All people, including those who require assistance to make their own decisions, should be respected and have the right to choose which treatments they receive.
2. **Beneficence** — People are treated in an ethical manner by respecting their decisions, protecting them from harm and making efforts to secure their well-being. Additionally, people should be protected from harm by maximizing benefits and minimizing risks in the research study.
3. **Justice** — All people should share the benefits and burdens of research.

All studies are directly supervised by physicians and research experts to ensure compliance with all scientific and ethical guidelines. These regulatory requirements for drug studies address safety and efficacy issues unique to the use of drugs in clinical research and are designed to guarantee the safety of all participants in a clinical trial. Every trial also has a local principal investigator whose name and phone number are on every trial and can be contacted. In addition, all investigators have required training and periodic updates of training.

Failure to meet the FDA's regulations can have legal and financial consequences for those conducting the research as well as for the institutions associated with the research activities. All drugs must pass a series of tests and undergo a rigorous evaluation process by the FDA's Center for Drug Evaluation and Research (CDER) to ensure they are safe and effective before being available to the public. A team of CDER doctors, chemists, pharmacologists and other scientists analyze the medications at various stages during the approval process. ■

Understanding the Informed Consent Process

➥ **Another key safeguard** is the Informed Consent process, which protects participants throughout the clinical trial. This process requires the research team to explain all the details about the trial, including the purpose, tests and treatment involved and the possible risks and benefits, so you can make an informed decision about volunteering for a trial.

The Informed Consent form will include some of the following information. A member of your health care team should further explain it in easy-to-understand language:

- The trial and its goals.
- Possible risks and benefits.
- How you will be monitored and what side effects to expect.
- The best standard regimen of care for the stage of your disease, regardless of the doctor or institution.
- The safeguards in place. All clinical trial participants are protected by rules that apply nationwide to all facilities.
- How to withdraw from the trial. You may choose to leave the trial at any time and for any reason.

To ensure you fully understand, you are required to review the form. You should have a reasonable amount of time to review the trial's information and ask questions before giving your consent. Before signing it, check with your insurance providers to determine the procedures that are covered and those you will be expected or required to pay out of pocket. Although many components of the trial may be covered, other expenses may be your responsibility. It is important for you to have this information before you begin participating in the trial.

Keep in mind that participants in a clinical trial are not guaranteed to benefit. And, as with any type of cancer treatment, potential risks as well as benefits may occur.

Make the time to understand the costs before joining

Every type of cancer treatment, including those being tested in clinical trials, has associated costs. But, before you allow the potential costs to affect your decision about including a clinical trial in your treatment plan, take the opportunity to learn about them. The more you know, the more prepared you will feel to make the important decisions ahead.

Patients often assume that clinical trials will be too expensive because they include experimental therapies. Frequently, this is not the case. When you receive the Informed Consent form for the trial, look it over carefully because a detailed list of the costs covered by the trial is included. Before you sign the form, address all your concerns about cost and payment. The clinical trial administrators will expect you to have questions, and they are prepared to answer them.

The costs related to clinical trials typically fall into two categories:

- Routine patient care, which applies to any type of cancer treatment including those used in clinical trials, usually involves expenses related to doctor visits, hospital stays and some testing procedures.
- Research costs are directly related to the clinical trial and are typically covered by the trial sponsor. They include drugs and procedures.

CONTACT YOUR INSURANCE PROVIDER

Review your policy and contact your insurance company. Also, verify that the costs not covered through the clinical trial will either be covered by your health insurance plan or be your responsibility.

Costs that typically are not covered by insurance include the cost of the treatment or procedure being studied in the trial and any procedure only needed to collect data for the study.

If you do not have insurance or are underinsured, assistance may be available. Ask the clinical trial administrators about patient assistance programs, and explore the resources in this guide (flip over this guide to see *Assistance & Support*, page 41). Many patient advocacy organizations may help offset the costs and navigate the often-confusing financial part of cancer treatment.

LOOK INTO GOVERNMENT ASSISTANCE

Some federal and state government programs may assist with the costs associated with a clinical trial. Start by checking into these programs:

- The Patient Protection and Affordable Care Act (ACA), a federal law that regulates health plans and insurance, covers routine clinical trial costs. Clinical trials covered under the ACA must be designed to study new ways to prevent, detect or treat cancer or other life-threatening illnesses. Check whether your insurance plan covers costs outside of your health plan's network.
- Medicare covers portions of clinical research studies, such as trials designed to evaluate a cancer drug's effectiveness. Medicare Part A and/or Part B may cover some, such as office visits and tests, in certain qualifying clinical research studies. Medicare Advantage plans may pay the difference in your out-of-pocket costs between it and traditional Medicare. Talk with your clinical trial administrators before proceeding to ensure you understand their recommendations, the costs and the covered expenses.
- TRICARE is the Department of Defense's health care program. In partnership with the National Cancer Institute (NCI), the Department of Defense now covers participation in Phase I, II and III NCI-sponsored cancer clinical trials as a TRICARE benefit.
- The U.S. Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored clinical trials at VA medical centers. ■

GLOSSARY | Terms to know

▸ ***As you consider a clinical trial, you will hear many new words. These definitions may help.***

Case manager: A personal advocate who collaborates with health care professionals and nonmedical personnel to help patients overcome various financial, logistical and other common barriers to care.

Claim: A request for payment you make to your insurance provider based on the terms of your policy.

Copay: The fixed amount, according to your insurance plan, that you must pay for specific types of medical care, usually at the time of service.

Deductible: The amount that you must pay for medical expenses before your insurance begins paying.

Eligibility criteria: The guidelines defining who can participate in the clinical trial based on several factors, which may include age, type and stage of cancer and treatment history.

Explanation of benefits (EOB): A statement your health insurance company provides to explain which medical treatments and/or services were paid on your behalf.

Financial counselor: A person who works with patients and their families to reduce stress or hardships related to treatment costs. This may include setting up payment plans, finding cost-saving methods and improving access to services.

HIPAA: The Health Insurance Portability and Accountability Act is a law that protects the privacy of your personal medical information.

Informed Consent form: A document that contains information about the clinical trial, including the potential benefits, risks and the alternatives to the research being conducted. You are required to review the document and sign the form to enroll in the trial.

Medicaid: A health insurance program for people who cannot afford regular medical insurance. The program is run by U.S. federal, state and local governments. People who receive Medicaid may have to pay a small amount for the services they get.

Medicare: A U.S. federal health insurance program for people aged 65 years or older and people with certain disabilities. Medicare pays for hospital stays, medical services and some prescription drugs. People who receive Medicare must pay part of their healthcare costs.

Out-of-network: The term given to health care providers or facilities not associated with your insurance plan. Their fees are typically more than in-network fees.

Out-of-pocket costs: Medical expenses you are responsible for paying. This may include deductibles, coinsurances and copayments for covered services, plus all costs for services not covered by your insurance plan or other entities.

Precertification: The process of getting approved by your insurance company for specific services, procedures or treatments before you have them.

Some definitions courtesy of the National Cancer Institute website (www.cancer.gov)