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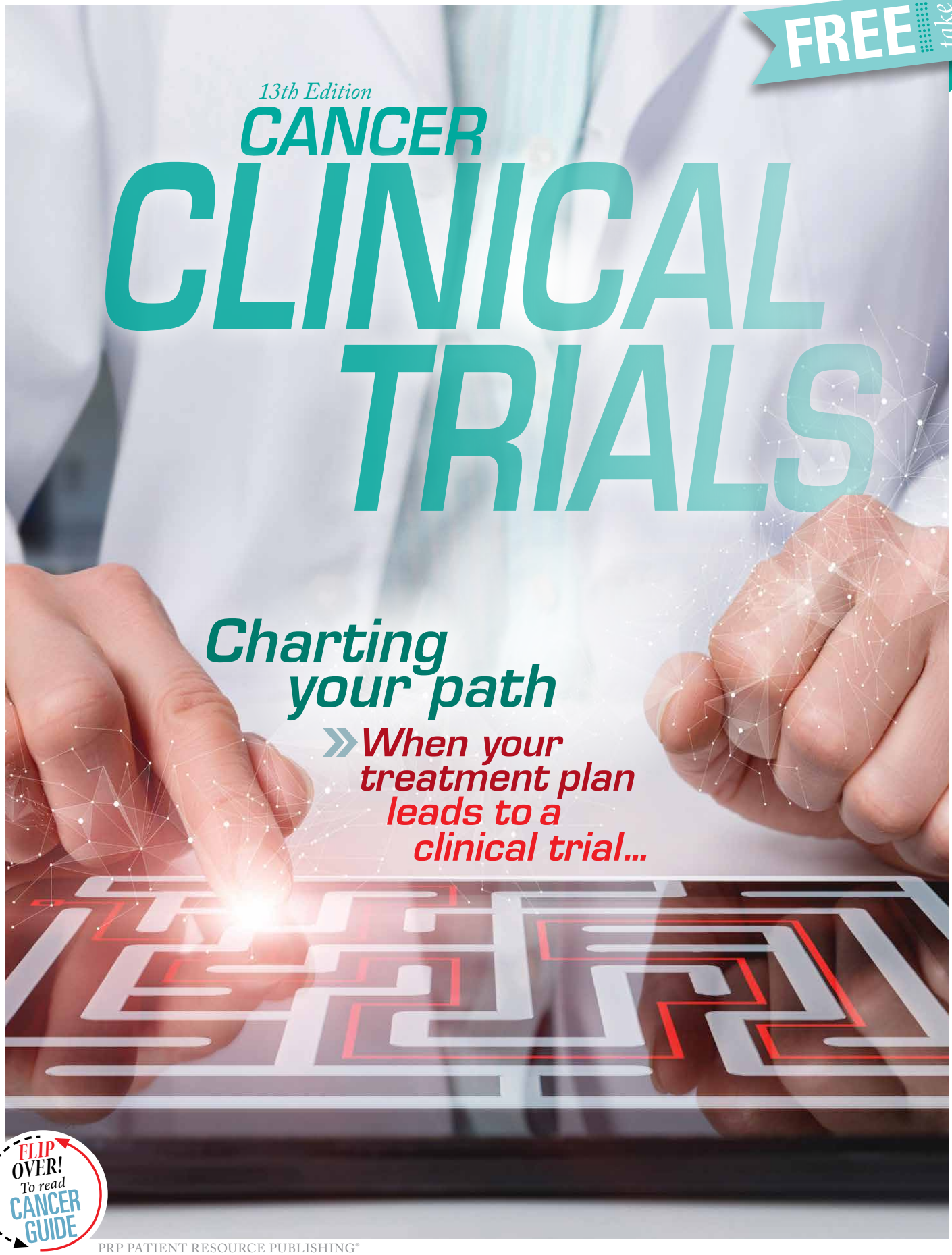
CANCER CLINICAL TRIALS



Charting your path

» When your treatment plan leads to a clinical trial...

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Luminosity Study: A study in patients with previously treated locally advanced or metastatic c-Met+ Non-Small Cell Lung Cancer

Non-Small Cell Lung Cancer Research Study

Do you or someone you know have Non-Small Cell Lung Cancer? Consider the Luminosity Study.

This research study is evaluating the safety and effectiveness of an investigational study medication, called telisotuzumab vedotin (ABBV-399), in Non-Small Cell Lung Cancer patients (NSCLC).

Patient Population

Subjects with locally advanced or metastatic c-Met+ NSCLC, who have progressed on systemic cytotoxic therapy (or are ineligible) and an immune checkpoint inhibitor (as monotherapy or in combination with systemic cytotoxic chemotherapy, or ineligible), and prior anti-cancer therapies targeting driver gene alterations (if applicable).

Patients Must Meet the Following Criteria

- 18 years of age or older
- Diagnosed with locally advanced or metastatic non-small cell lung cancer
- Has histologically documented non-squamous cell NSCLC
- Tumor must not carry an EGFR mutation
- Completed one or two rounds of chemotherapy and the cancer has gotten worse during or after treatment
- Test positive for c-Met protein expression as assessed by an AbbVie designated IHC laboratory (AbbVie will perform this test at any time during previous treatments, even before the cancer has gotten worse)
- Does not have adenosquamous histology
- Has not received prior c-MET-targeted antibody-based therapies
- Other criteria apply*

*The study doctor will tell you about additional requirements to be able to participate in this study.

For more information, ask your doctor about the Luminosity Study or visit **https://ClinicalTrials.gov** (NCT03539536) to learn more about this study.

ABBV-399 is an investigational drug that is not approved by the FDA or other global health authorities. Safety and efficacy have not been established.

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CANCER CLINICAL TRIALS

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IN THIS GUIDE

Sheila Marie Johnson, *clinical trial participant & breast cancer survivor, page 3*

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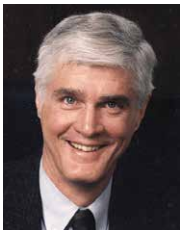

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Introducing clinical trials...

When considering your treatment path

Receiving a cancer diagnosis may make you feel as if you have entered a maze full of twists and turns with no clear way forward. Rest assured that your doctor and health care team will be there to lead you down a brightly lit path to find the best treatment for you. As your doctor adapts your treatment plan to your cancer's behavior and the effectiveness of current therapies, a clinical trial may be an option to consider. Regardless of where you are in the continuum of care – newly diagnosed or ready for a new option – your team will guide you through the process if a clinical trial is the next step.

Unless you have a friend or loved one who has been involved with a clinical trial, you may not know much about them. Because there are so many myths and misconceptions about clinical trials, it is important to become informed. Before missing out on this valuable option, talk about clinical trials with your medical team and others who have experience with them. Use the information in this guide and other trusted resources to learn more about trials, what they offer, and how they may benefit you. Knowing more will help you feel more equipped to make the decisions ahead.

WHAT ARE CLINICAL TRIALS?

Clinical trials are research studies that test a new medical approach, and they are frequently used in cancer treatment. 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).

At any given time, thousands of clinical trials are underway to identify new and better ways to treat cancer and its symptoms and side effects, including new drugs, drug combinations, medical procedures or devices. These are known as therapeutic clinical trials and are the type that most people are familiar with. Additionally, other non-treatment trials evaluate the following:

- Disease prevention and patient screening methods
- Diagnostic tools and procedures
- Genetic risk factors
- Ways to improve health and/or quality of life

This guide focuses on therapeutic trials. If you are interested in learning more about non-treatment trials, talk with your doctor.

WHEN TO CONSIDER A CLINICAL TRIAL

Mistakenly thought of as last resorts, clinical trials actually may be incorporated into your treatment plan at any time.

In some cases, a clinical trial may be your best first treatment option, especially if your diagnosis has few or no approved therapies. A trial may also be desirable if your current treatment becomes less effective, stops working or has side effects that disrupt your quality of life.

Sometimes, when cancer progresses, genomic testing may reveal a new mutation that may make you eligible for clinical trials testing therapies designed to treat that specific mutation.

TWO TEAMS OFFER MORE OVERSIGHT

When you take part in a clinical trial, you have the benefit of being cared for by two groups of medical professionals: your usual health care team and your clinical study team. These experts will work together to coordinate your care.

Clinical trials are led by a principal investigator, who is often a medical doctor. A research team that generally includes doctors, nurses, social workers and other health care professionals is also involved with various aspects of the trial.

Throughout the trial, you will continue to have your regular health care needs met by your original health care providers. Their involvement helps ensure the clinical trial does not conflict with medications or treatments that you receive for other conditions. ■

The Four Phases of Therapeutic Trials

➥ **You may be concerned** that because clinical trials are not approved, they are not safe. On the contrary, clinical trials go through extensive testing before they are deemed safe.

Generally, the studies happen in four phases. 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 researched are approved for the public.

Based on the successes of other trials, the FDA recently has shortened its approval times for new therapies. 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 the earliest possible access to lifesaving treatments.

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 and when the drug should be given, and the dosage that will 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.

Survivor promotes clinical trials for the greater good

Sheila Marie Johnson ***was diagnosed de novo (at first occurrence) with Stage IV breast cancer at 43. She immediately began treatment, but over time, the cancer progressed. After the fourth progression, her doctor recommended a clinical trial. Today, Sheila's cancer is stable, and she is passionate about encouraging other African American women to consider clinical trials.***

Being diagnosed with metastatic breast cancer is a day I will never forget. My mother had passed away in 2004 from metastatic breast cancer, and now I was facing the same thing. It was devastating.

It started when I sneezed and felt a strange burning sensation in my chest. When it happened again a couple weeks later, I saw my doctor and had a mammogram. I knew something was wrong when the technician asked me to sit down. The radiologist pointed to the scan. The white areas in my breast were cancer and the burning sensation I felt was the cancer that had already metastasized to my ribs.

At the time, I was actively serving in the Air Force and hoped to become a chief master sergeant. Military bases don't have oncology doctors, so I was sent to a cancer center. Biopsy results there determined the breast cancer was *ER+*, *PR+*, *HER2+*. Additional scans showed the cancer had also spread to my liver.

After consulting with a breast surgeon, I asked for a mastectomy. She was reluctant, though, because she thought there was no need since the cancer was already in my bloodstream. Instead she recommended removing my ovaries because my cancer was driven by hormones. Then she referred me to a medical oncologist, who started me on chemotherapy. Because my cancer was driven by hormones and *HER2*, I started hormone therapy and anti-*HER2* targeted therapy as well. This would be my treatment plan as long as it was effective.

Though I had my ovaries removed, I kept pressing for a mastectomy. Eventually, my oncologist took my information to a tumor board. They didn't see any reason not to have a mastectomy, so I proceeded with surgery to remove my right breast and had a breast reduction of my left breast. When my reconstructive surgery with expanders didn't work because of infection, I switched to wearing a prosthesis. Later, I had the DIEP flap procedure, which made me look and feel more normal.

My condition was relatively stable for some years, but, over time, the cancer stopped responding to the treatment. We needed to explore other options. After my cancer progressed for the fourth time, my doctor offered the opportunity to enroll in a clinical trial. I trust my doctor completely, and I agreed.

I feel blessed to have a doctor who suggested a clinical trial. It made me trust her even more because it showed she had my best interests at heart. The trial she recommended was testing a new anti-*HER2* targeted therapy for metastatic *HER2+* breast cancer. I did some research, took the Informed Consent form home to read more about it and decided to join the trial.

The targeted therapy reduced the cancer, but I had a lot of nausea. Communicating with the trial team was crucial. When I told them, they began giving me fluids before treatment, which really helped. And, when some other side effects became severe, they reduced the dose so I'd be more comfortable. I am beyond grateful that I have a medical team that listens. It's made my quality of life so much better.

I stayed in the trial until I had to leave because of COVID-induced pneumonia. I took a short break from treatment and have since returned to chemotherapy.

Would I opt for a clinical trial again? Absolutely!

I tell everyone who will listen that participating in clinical trials is important and valuable. Just by participating in a clinical trial, you are contributing to the future of cancer care. And people of color are especially needed. That is why I am passionate about encouraging other African Americans to consider participating. I share this message on social media, with cancer organizations, and at speaking events.

From my research, African American women very seldom participate in clinical trials for a number of reasons: lack of awareness, communication issues with their medical team, economic factors and distrust.

To combat that skepticism, I remind them that every cancer medication was once approved through a trials process. Someone had to take that medication before them. These medicines go through a rigorous amount of testing.

Clinical trials also offer you the opportunity to try a new drug that may be covered by the trial or your insurance. That can save you the cost of the new medication — and cancer medications can be very expensive.

If your doctor doesn't discuss clinical trials with you at the first couple of meetings, ask about them, even if you aren't interested in participating at the time. You never know when a clinical trial may be your best option. It could even save your life. ■

Be informed and get involved in the search

Clinical trials offer you the opportunity to be a proactive partner in your own care. First, let your doctor know you are open to considering a clinical trial. While a member of your health care team works behind the scenes to identify trials that may benefit you, you can search on your own. Not only will you become more informed about the research studies that are happening, you may find the next step in your treatment plan.

GETTING STARTED

To begin, have your exact diagnosis, pathology report and details of previous treatments available. These will help you narrow the list of trials that may be a good fit for you. Then, you have two options:

1. **Search online.** Many websites offer ways to search for a clinical trial. Some are customized to a certain cancer type; others are much broader. Generally, clinical trial search sites are hosted by the government, the National Cancer Institute, cancer advocacy groups, pharmaceutical companies and industry trade organizations, academic medical centers and major hospitals. No single list contains every open clinical trial, and new trials are continually being added, so check back often. Depending on your diagnosis, there could be hundreds of trials to explore. That will take time, so consider taking the "divide and conquer" approach by asking friends and family members to help (see *Clinical Trial Resources* on this page).
2. **Request assistance by phone.** This is convenient for people who are not tech-savvy, do not have access to the tools necessary to search online or simply prefer to talk to a person.

Your search will likely begin with eligibility questions. Every participant in a specific trial must meet the same eligibility criteria. This ensures the data gathered during the trial is valid.

Common criteria include cancer type, subtype, stage, biomarker status and treatment history. Your age, gender and other health conditions may also be factors. Keep in mind that you may not qualify for every trial that appeals to you. Some may be closed, or you may not meet eligibility criteria. For example, if a trial requires that you have already had a specific treatment and you have not, you will not be eligible.

Under certain extreme conditions, you and your doctor may apply to the U.S. Food and Drug Administration (FDA) to join a clinical trial that is closed or otherwise inaccessible. This is known as Expanded Access, also called Compassionate Use.

READING YOUR SEARCH RESULTS

You will see a list of trials that match your criteria. Each clinical trial will contain details specific to that trial.

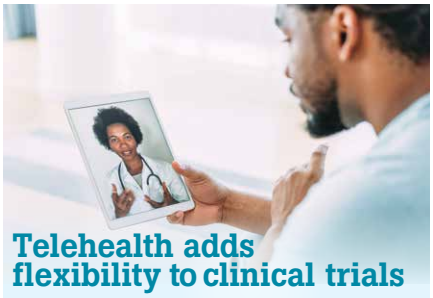
The study description explains the purpose of the clinical trial and the treatment being studied. This section is usually written for health care providers, so it may be difficult to understand. If it is, print out the information to discuss with your doctor.

Also included are the specific 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.

Be aware that new trials are added and the trial status changes frequently, so check often for updates. Once you find one or more trials you are interested in, talk with your doctor. ■



Telehealth adds flexibility to clinical trials

➥ It is a common misconception that you have to travel to a large medical center to take part in a clinical trial. Many are held across the country in hospitals, doctor's offices and treatment centers of all sizes. Even with these options, you may find a clinical trial that is not located in your area. Don't let this stop you. Now, a clinical trial may offer the option to be done via telehealth.

Also referred to as virtual appointments, 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.

Along with being convenient and offering access to more clinical trials, telehealth is making trials more flexible, less expensive and more equitable. Other advantages include the following:

- 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.
- Increasing access to specialists including dietitians, psychologists and other health professionals.

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

Viale-m

Post-chemotherapy combination maintenance clinical trial in AML

Randomized, Double-Blind, 2-Arm, Multicenter, Phase 3 Clinical Comparative Study of an Investigational Combination vs Single Agent Maintenance Therapy for Patients With Acute Myeloid Leukemia in First Remission After Conventional Chemotherapy (VIALE-M)

Being treated for Acute Myeloid Leukemia?

Consider the VIALE-M Study.

The goal of the VIALE-M Study is to evaluate the safety and efficacy of an investigational combination of drugs in patients who meet the following criteria:

- 18 years of age or older
- Newly diagnosed with Acute Myeloid Leukemia treated with conventional chemotherapy
- Achieved first remission (CR or CRi) within 120 days of enrollment or no more than 75 days since last dose of conventional chemotherapy
- Have not had, and are not planning, a stem cell transplant

If you or someone you know meets these criteria and may be interested in participating, please visit **www.AbbVieClinicalTrials.com/M19-708**.

NCT04102020

Weaving your way through Informed Consent

Once you find a clinical trial, the next step is to review and sign the Informed Consent form. You may find the word "form" misleading because the Informed Consent form is often not a single page. It can be up to 20 pages or more, but do not worry. You are not expected to wind your way through this complex maze of paperwork alone. A member of the clinical trial team will guide you, answering your questions along the way. This information helps you decide whether the trial is right for you.

Informed Consent is a safety measure designed to protect participants throughout the clinical trial. Before being distributed, the consent form is reviewed and approved by several groups consisting of members of the scientific community and lay individuals. The format is an organized way for the research team to explain all the details about the trial, including the purpose, tests and treatment involved.

WHAT IS INCLUDED IN INFORMED CONSENT?

Because every clinical trial is unique, each has its own Informed Consent form. The form for the specific trial you are considering contains customized information about that trial, such as the modality (method of treatment) being tested, dosage/frequency, schedule of appointments and more.

Generally, the following key information is included on every Informed Consent form:

- The trial and its goals.
- Possible risks and benefits. As with any type of cancer treatment, potential risks as well as benefits may occur. Keep in mind that there is no guarantee that the treatment will be effective for you.
- How you will be monitored.
- Potential side effects to expect.
- The best treatment regimen, referred to as standard-of-care treatment, for the stage of your disease, regardless of the doctor or institution.
- The costs that are covered by the trial and those that will be your responsibility.
- The safeguards in place (see *Safety Measures,* page 7).
- How to withdraw from the trial. Even after you begin a clinical trial, you are not locked in. Participation is always voluntary. You can leave the trial at any time and for any reason, and opt for standard-of-care treatment.

NEXT STEPS

To ensure you fully understand the components of the clinical trial, you are required to review the Informed Consent form before signing. You should have a reasonable amount of time to read the information at home. As you do, take notes and make a list of questions to ask.

Next, schedule an in-person or telehealth meeting with the clinical trial team to talk in detail about the trial and ask your questions. You are encouraged to have a family member or friend attend with you. It helps to have another person hear the same information. If English is not your first language, this is the time to request the assistance of a translator at the meeting.

The goal of the meeting is to ensure you fully understand the information so you can make a confident and informed decision. If at any time you find the medical terminology or any other aspect of the trial confusing, simply ask. A member of the team will explain it in easy-to-understand language. Be sure to take notes to refer to later.

After the meeting, check with your health insurance provider to determine the procedures that are covered and those you will be expected or required to pay out of pocket (see *Financial Considerations*, page 7). Although many components of the trial may be covered, other expenses, such as travel, lodging, food, parking and more, may be your responsibility. It is important for you to have this discussion before you begin participating in the trial.

You may request additional time to consider what you have learned or to talk it over with loved ones. If you choose to move forward, let the team know that you are ready to sign the Informed Consent form.

REVISITING INFORMED CONSENT

Sometimes it is necessary to revise the Informed Consent form and ask participants again for their consent when changes are made to the clinical trial, such as modifications to procedures or changes to the risks and benefits. Trials are required to alert participants. This is a protective measure. Participants must be made aware of any information that may help them decide whether they should continue with the trial. ■

Questions to Ask Your Clinical Trial Team

1. **What is the schedule of appointments? Will I have to adjust my work, school or other schedules to accommodate the trial?**
2. **Is travel required? Is telehealth available for any parts of the trial?**
3. **What type of reporting will I be responsible for?**
4. **Will the potential side effects affect my quality of life?**
5. **How long is the trial expected to last?**
6. **Could I speak to someone who has participated in a clinical trial?**
7. **Could you refer me to a financial representative on the clinical trial team?**

The last turn in the maze:
Understanding the costs involved

Many people assume that clinical trials will be too expensive because they include experimental therapies. It may surprise you to learn that several costs are covered by the clinical trial. The Informed Consent form includes details about the costs the trial will cover, and you can request a list of the services and tests that will take place at each study visit. Your team will be available to answer any questions.

In general, 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, laboratory and imaging tests for research purposes and procedures.

After learning the costs you will be responsible for, the next steps are to determine the expenses your insurance will cover and to look into alternative forms of assistance if needed.

INSURANCE COVERAGE

Contact your insurance company to verify which costs not covered by the trial sponsor will be covered by your health insurance plan or will be your responsibility.

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.
- Medicare covers portions of clinical research studies, such as a cancer drug's effectiveness. Medicare Part A and/or Part B may cover some items, such as office visits and tests, in certain qualifying studies. Medicare Advantage plans may pay the difference in your out-of-pocket costs between it and traditional Medicare.
- TRICARE is the Department of Defense's health care program in partnership with the National Cancer Institute (NCI).
- The U.S. Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored clinical trials at VA medical centers.

PATIENT ASSISTANCE PROGRAMS

If you do not have insurance or are underinsured, assistance may be available. Ask the clinical trial's administrators about assistance programs, and explore the resources in this guide (flip guide over to see *Assistance & Support*, page 37). ■

Layers of protection ensure participants are safe

People are often concerned about safety when the conversation turns to clinical trials. Participation brings risks and benefits — some known and some unknown. But every patient who joins a clinical trial is protected by multiple safety measures and guidelines. These rules create a safety net of support to keep participants safe.

The safeguards established include 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. 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 must follow the same protocol.

Following are some of the layers of safety involved with clinical trials.

The U.S. Food and Drug Administration (FDA) is responsible for the safety, efficacy and security of drugs. The FDA monitors the drug development process and works closely with pharmaceutical companies to ensure the integrity of new treatments and medications. 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.

Institutional Review Boards (IRBs) are groups that review each clinical trial's protocols before the study begins and monitor the trial's ongoing progress from beginning to end.

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.

Physicians, research experts and investigators directly supervise all studies. This extra safety measure is designed to ensure compliance with all scientific and ethical guidelines.

The National Research Act established regulations that led to the creation of these basic ethical guidelines:

- 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.
- 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.
- Justice: All people should share the benefits and burdens of research. ■

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