Fifth Edition
UNDERSTANDING CLINICAL TRIALS
A GUIDE FOR PATIENTS AND THEIR FAMILIES
WHERE INFORMATION EQUALS HOPE
CONTENT REVIEWED BY A DISTINGUISHED MEDICAL ADVISORY BOARD

PRP PATIENT RESOURCE PUBLISHING
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 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 three lines of therapy, including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), daratumumab, and glucocorticoids. Daratumumab combination regimen must be one of the prior lines of therapy
• Other criteria apply

For more information ask your doctor about this study or visit www.clinicaltrials.gov (NCT#01794520) to see if you qualify.
1. Talk to your health care team about managing the stress. This battle is too tough to fight alone.

~ Kim Schuetz

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Scientists and doctors are conducting research to learn new ways to prevent, diagnose and treat cancer. Many of the advancements in cancer treatment today are a result of the medical research performed in clinical trials. Depending on your diagnosis and other factors, a clinical trial may be an option to consider.

Although you may not know much about clinical trials, the information in this guide, along with input from your doctor, will help you understand more about them and what they may mean for you. There are three types of clinical trials.

1. Treatment Trials evaluate whether a new type of treatment (drug, surgery, radiation therapy) or a combination of treatments is better than the currently approved treatments being used.

2. Quality-of-Life Trials study ways to improve the quality of life for people being treated for cancer and cancer survivors who experience cancer-related and treatment-related symptoms. This type of trial may evaluate the effects of such things as nutrition, group therapy or counseling.

3. Prevention, Screening and Diagnostic Trials assess ways to reduce the chance of getting cancer in general. In these trials, which may be treatment or non-treatment trials, many participants do not have cancer, but some have had cancer and are at risk of it returning (recurring) or a second cancer developing. Sometimes these trials consist of simply completing questionnaires and providing medical information.

WHAT TO EXPECT
Clinical trials are carefully thought out, planned and performed in a consistent manner so that all patients are treated exactly the same, from medication dosage and schedule to the frequency of follow-up appointments. Institutional review boards or ethics committees carefully set up safeguards to make sure that all patients in the clinical trial remain safe throughout the process.

Whether you’re at a small rural hospital or a large facility in a metropolitan area, your medical team is responsible for diligently following all of the same protocols and safety measures for your treatment plan across the board.

When you volunteer to participate in a clinical trial, you will receive specific instructions, and you are also encouraged to ask questions about anything you don’t fully understand. This is the ideal time to talk with your medical team about the many falsehoods that persist about clinical trials. For example, although there is fear to the contrary, participants are guaranteed to receive, at minimum, the current standard of care during the trial.

BENEFITS AND RISKS
Clinical trials present many potential benefits, such as the opportunity to access leading-edge treatments that aren’t yet widely available. They may be an alternative if your current treatment isn’t working as well as it once was, or if you have a rare type of cancer that hasn’t been studied as much as others. You will also be more closely monitored in a clinical trial by your regular oncologist and the clinical trial medical team, which means that side effects or other problems may be noticed and addressed earlier. Even after treatment ends, you will be in close contact with the medical team.

At the same time, trials can present potential risks or inconveniences. Almost every type of cancer treatment has side effects, and those in clinical trials are no different. Ask your medical team about what to expect. You may have more frequent tests or medical visits, for example. Make sure you are aware of the necessary schedule associated with the trial to be sure you can accommodate it.

THE FOUR PHASES OF CLINICAL TRIALS
Clinical trials are conducted in four phases, and each phase is designed to address a separate research question about the treatment being evaluated. The information gathered in each phase helps build the next phase, providing researchers with the most reliable information possible.

By completing the phases in order, researchers are able to learn about treatments while keeping participants as safe as possible.
When Dr. Hong talks with patients about treatment options, he understands they may not know much about clinical trials. His first goal is to educate.

“I outline the purpose of the clinical trial we’re considering, and we discuss pros and cons. I talk with patients about the key benefits of clinical trials, such as having access to new drugs that aren’t yet commercially available. I also let them know they may get more focused care when they’re in a clinical trial because of all the protocols and guidelines that must be followed rigorously. And, because clinical trials are more widely available now, it is possible one can be found near where they live. If not, however, I wouldn’t hesitate to recommend going to a larger center.”

The financial aspect of treatment is always a concern, too, and clinical trials are sometimes paid for by the trial organizer.

“That can be an incentive because patients are monitored more closely with additional tests and appointments but do not have to pay out-of-pocket for them.”

Dr. Hong also talks about the big picture contributions that people make by being part of a clinical trial.

“The results we obtain in terms of outcome can be applied to other cancer patients. But,” he warned, “we have to be careful because people are anxious about their own situation and may not be thinking about others at that point, which is understandable. It’s like the old saying, ‘You have to put out the fire in your own house before you put out the fire next door.’”

To help ease their nerves, Dr. Hong talks with patients as he would with friends or colleagues, and he stays close, always ready to address any concerns.

“People often fear they are going to be guinea pigs, but I let them know that is not the case. We’re not asking them to do that. But, as doctors and researchers, we are not fully satisfied with today’s cancer treatments. Our job, ultimately, is to make progress. To make that progress, we must conduct clinical trials.

“To calm their fears, I present very clearly that these clinical trials are an opportunity to receive new treatments that are potentially better than standard treatments, not inferior to them. The important part is to explain the nature of a clinical trial and what goes into one. It is a tremendously time-consuming effort that has been put together by many people.”

After sharing all these details and talking through the Informed Consent form, Dr. Hong recommends they take time to think about everything.

“I never push the patients. I encourage them to talk it over with their family and do research on their own.”

When patients are making this important decision, they sometimes ask Dr. Hong if he would take part in a clinical trial.

“Knowing the history of medicine and of clinical trials, I can honestly tell them I would, especially if my existing treatment was not satisfactory.”

According to Dr. Hong, the many opportunities we have today for innovative, novel clinical trials makes this a very exciting time.

“In the old days, we had surgery, radiation and chemotherapy. Now we have new drugs and new targeted agents – we have many menus on the table – and we have bright, highly motivated young people who are jumping right in with contributions. Today’s clinical trial may be tomorrow’s standard treatment.”
1 Many advances made in cancer treatment today are the result of clinical trials. The research that happens through clinical trials helps identify the treatments that work best for certain illnesses or groups of people. Those treatments are called “standard of care,” which are treatments that experts agree are the most widely used and appropriate therapy for a particular type and stage of cancer. See Words to Know, page 8, for definitions of many terms used in clinical trials.

Clinical trials deserve the same consideration as other treatment options. Considering a clinical trial is valuable for many reasons. You may have a rare type of cancer that hasn’t been studied as much as other types. Your current treatment may not be working as well as expected. Or, a clinical trial may significantly improve your quality of life. In a clinical trial, you will be closely monitored by your regular oncologist as well as the clinical trial medical team.

You can make a valuable contribution to the future of cancer care. Simply by participating, you play an integral role in helping refine and improve the way millions of people with all types and stages of cancer are treated. You will not only help identify treatments that work, but also eliminate those that don’t.

Safety measures are followed and required. Clinical trials offer opportunities for gaining access to cutting-edge treatments that are not yet widely available and, due to the testing nature of them, they are highly regulated. An entire agency in the U.S. Department of Health and Human Services, known as the U.S. Food and Drug Administration (FDA), is charged with ensuring the safety, efficacy and security of human drugs, in addition to other areas of regulatory authority. The FDA has regulated the conduct of clinical trials since the 1970s, and the protection of human participants in research is a primary focus. To ensure compliance, all studies are conducted under the direct supervision of physicians and expert research professionals, and every participating clinic, hospital, university or cancer center, regardless of size or location, is subject to the same protocol (see Safety Measures, page 7).

Placebos are not substituted for care. No matter what treatment you receive during the trial, you are guaranteed to always get the current standard of care. That means you will never get a placebo instead of cancer treatment, and you won’t jeopardize your medical care if you participate.

More locations offer trials than you might think. Clinical trials take place in big cities, rural areas and many places in between. Although some people may have to travel for clinical trials, others take advantage of them in local hospitals, treatment centers and even doctors’ offices. If a clinical trial you find happens to be in a different city, check out the resources available for lodging during treatment. They may help cover the cost of temporarily relocating while you’re in the trial (see Transportation & Travel Resources, page 50). Don’t rule out a clinical trial because of its location until you’ve checked into all the details.

You can leave a trial at any time. Participation is always voluntary, even after the study begins. Although you sign an agreement saying that you understand the potential risks involved and agree to join, you can change your mind at any time. If your expectations aren’t met or if you have too many side effects, you can withdraw and return to standard of care treatment.

Be proactive. You can search for available clinical trials. You don’t have to wait for your doctor to recommend one. Online resources make it possible to search clinical trials by cancer type and other key factors. Many patients take the “divide and conquer” approach, enlisting the help of friends and family to research trials all over the country (see Searching for a Clinical Trial, page 5).

New clinical trials are opening up all the time. If you discover that a trial you’re interested in is closed (not accepting any more participants), talk with your doctor and continue to check your sources. New trials get underway in different locations often.

The decision is yours. Before deciding whether to participate, do your research. Consult with your own doctor as well as the health care team who will be conducting the trial. Talk with other clinical trial participants about their experiences, but keep in mind that no two experiences will be exactly alike. You can, however, find out what it’s like to receive care within a clinical trial. Also, check with your insurance company to see what your policy covers and what you will be required to pay if you participate. Regardless of the opinions and research you gather, participating in a clinical trial is ultimately your decision.

“Patients can expect clinical trials to follow a very regimented process, from the amount of medication they take and the time it is taken to being monitored very closely for side effects and changes in the tumor — more so than if they were not participating in a clinical trial.”

Roy Jensen, MD, is the Director of The University of Kansas Cancer Center, Professor of Pathology and Laboratory Medicine, Cancer Biology, and Anatomy and Cell Biology at The University of Kansas School of Medicine, and the William R. Jewell Distinguished Kansas Masonic Professor.
Thousands of clinical trials are happening at the same time, and finding a trial that may be a fit for you can be confusing. Understanding how to navigate an online clinical trial site, and enlisting the help of friends and family to help you, can make your search much less overwhelming.

Below are screenshots from a mock clinical trial search site to give you a general idea of what to expect and help you decipher the medical jargon that may be difficult to understand. Each clinical trial has certain criteria you must meet to be eligible to participate. Before you begin, have your exact diagnosis, pathology report and details of previous treatments handy.

If you find a clinical trial that appears to be a good fit but is no longer accepting patients, you may be eligible for expanded access. Also referred to as compassionate use, this is a program that extends the access of an investigational treatment or medical product outside of its use in a clinical trial. To obtain permission, your doctor must submit an application to the U.S. Food and Drug Administration (FDA) and permission must be granted by the company that provides the medical product. If you don’t find a clinical trial, know that new clinical trials are being added all the time. You may choose to continue searching while you move forward with your current treatment plan.

### [STEP 1] FILL IN YOUR INFORMATION

#### Enter Your Diagnosis
You may conduct multiple searches to create more options. For example, first enter the diagnosis, such as “Stage IV breast cancer” and do the search. Next, try “Advanced breast cancer” then “Metastatic breast cancer” to compare the different results.

#### Location
If you prefer to find a clinical trial that is close to home, enter your home address. If you are willing and able to travel for treatment, enter other locations. Again, you can try multiple options.

### [STEP 2] READ YOUR SEARCH RESULTS

The name of the clinical trial will appear at the top of the results page.

#### Recruitment Status
This indicates whether the trial is actively recruiting, not yet recruiting or otherwise inactive. This will change, so continue to check for status updates.

#### Summary of Study
This contains detailed information about the clinical trial’s purpose and the treatment being tested. This section is usually written for health care providers and may be difficult to understand. That’s ok. If you find a clinical trial that interests you, print out the information so your doctor can explain it to you.

### FIND A CLINICAL TRIAL

These online resources are available to search for clinical trials that may apply to you.

- Center for Information and Study on Clinical Research Participation: www.searchclinicaltrials.org
- CenterWatch: www.centerwatch.com
- ClinicalTrials.gov: www.clinicaltrials.gov
- Clinical Trials and Me: www.clinicaltrialsandme.com
- Lazarex Cancer Foundation: www.lazarex.org
- My Clinical Trial Locator: myclinicaltriallocator.com
- National Cancer Institute: www.cancer.gov/about-cancer/treatment/clinical-trials/search
- TrialCheck: www.trialcheck.org
Austin and his mom, Kim, spent Mother’s Day in 2011 with grandparents while Austin’s dad, Jeff, enjoyed opening day of fishing season. When Grandpa pointed out lumps on Austin’s neck, Kim saw that they were the size of golf balls. As a registered oncology nurse, her stomach plummeted.

That Monday, Kim asked the pediatrician if it could be cancer. He looked her in the eye and said, “Kids that look this good don’t have cancer.” He diagnosed Austin with an ear infection and strep throat and prescribed antibiotics.

After a couple of days, Kim followed her gut and took Austin to a different pediatrician, who sent him to the emergency room for additional examinations. He told Kim and Jeff that he suspected Austin had leukemia. Even though she wasn’t overly religious, she asked for a chaplain to pray for Austin.

Austin was transferred immediately to a family children’s hospital about four hours away. The next morning, he had a bone marrow biopsy, and the results confirmed he had acute lymphoblastic leukemia. A PICC line was set, and Austin began chemotherapy that day. The steroids given with chemotherapy caused his stomach to throb and gave him unrelenting nausea. They also increased his appetite, and he gained weight rapidly. Muscle pain and body aches lasted for a month, but the treatment worked.

Austin mostly stayed in good spirits throughout his treatment. He resumed pre-school and daycare. When his brown hair began to fall out, it didn’t bother him, but it was a daily reminder to Kim and Jeff that their son had cancer.

He relapsed on October 18, 2012. The only option was a bone marrow transplant. They relied on the generosity of an unnamed 51-year-old male stem cell donor. Before the transplant, hunger and exhaustion got the best of Austin. “I don’t want to go to ‘heavens’,” he said. “I want to stay with you and daddy forever.”

Just a day after the transplant, he was running through the hospital halls ways playing cops and robbers. Mouth sores developed, but medications helped. He stayed in near-isolation at home for six months with hospital visits for weekly tests. As rough as it was, Kim looks back fondly on this time. Austin had many visitors, and Pet Pals brought in trained dogs to visit the kids. Austin bonded with a floppy-tongued dog named Elvis.

On day 92 after the transplantation, Austin relapsed. The doctors found a chimeric antigen receptor (CAR) T-cell therapy clinical trial in Philadelphia for pediatric and young adult patients with B-cell acute lymphoblastic leukemia. He had to be six months post-transplant, but his T-cells had to be removed immediately to protect his native cell population from the cancer. While they waited for the six months to pass, Austin rode his favorite roller coasters and visited the petting zoo. All activities came with facemasks and hand washing.

They relocated to Philadelphia for six weeks. Austin began chemotherapy. On October 1, Austin became patient #21 in the trial, and he began receiving infusions of his re-engineered T-cells. Side effects included a low-grade fever, restlessness, headaches, body aches and an upset stomach.

While they waited for the “all clear” from the hospital, they visited the Liberty Bell and the “Rocky” stairs. They attended an Eagles football game, at which Austin met another CAR-T patient in the trial (#22). The two boys stood on the field, smiles plastered across their faces, as the players rushed the field.

It was Halloween and Kim’s birthday when Kim got the call that Austin was cancer-free. He was trick-or-treating ahead of her, and she burst into tears.

Kim and Jeff encourage others to recognize the emotional aftereffects of having a young child with cancer. They acknowledge that it gets easier over time, but the worry never goes away. They recommend talking to your child’s health care team about ways to manage the stress. Heroes never fight a battle alone.
SAFETY MEASURES

Clinical trials have rules and protocols to safeguard and ensure your safety throughout the clinical trial process. Three main groups are responsible for making the rules that keep participants safe in clinical trials. They include Institutional Review Boards (IRBs), the U.S. Food and Drug Administration (FDA) and the Data and Safety Monitoring Board (DSMB).

IRBs check to see that clinical trials are designed correctly and are safe and fair. The safety, efficacy and security of human drugs are the responsibility of the FDA. The conduct of clinical trials has been regulated by the FDA since the 1970s, with the primary focus on protecting people who participate in clinical trials. The DSMB oversees clinical trials and ensures that they are safe for participants.

SAFETY GUIDELINES

All clinical trials evaluating a potential new drug or treatment seeking FDA approval must comply with scientific and ethical guidelines when the trial is being developed and monitored. To ensure compliance, all studies are conducted under the direct supervision of physicians and expert research professionals.

Drug safety is the number one priority of the FDA. As a result, the FDA works closely with pharmaceutical companies to ensure the integrity of new treatments and medications. Several steps in the drug development process are monitored by the FDA, which requires extensive research and applications before and after clinical testing.

All participating clinics, hospitals, universities and cancer centers, regardless of size or location, are subject to the same protocol. The protocol is a set of documented rules that outlines the eligibility criteria, specifies the tests that will be used and the procedures that will be performed, describes the medications and their doses, and establishes the length of each study.

These regulatory requirements for drug studies address the safety and efficacy issues unique to the use of drugs in the clinical research setting and are in place to guarantee the safety of all participants in a clinical trial. Failure to meet the FDA’s regulations can have legal and financial implications for those conducting the research as well as the institutions associated with the research activities.

Regardless of how or why drugs are developed or discovered, they all 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 for human use before they’re made available to the public.

BENEFITS VS RISKS

A team of CDER doctors, chemists, pharmacologists and other scientists carefully analyze the medications at various stages during the approval process. When the health benefits of a drug are found to outweigh the known risks, approval to move forward is granted. However, when issues arise, the process is delayed or even stopped. Some common problems that could prevent or delay a drug’s approval include the following:

- Unexpected safety issues
- Failure to prove the drug’s effectiveness
- Failure to follow good manufacturing practices
- Inability to accurately mass-produce the drug (resulting in quality-control issues, for example)

If one or more of this type of issue is identified, the CDER will send a letter to the drug sponsor (the pharmaceutical company) to explain the issue(s). Upon receipt of the letter, the drug sponsor can choose to meet with a CDER official for further discussion, ask for a hearing, correct the problem(s) and submit new information, or withdraw the application altogether.

MYTH VS FACT

Learn the truth about clinical trials

MYTH A clinical trial must be recommended by a doctor.

FACT You, or your doctor, can suggest a clinical trial. You are encouraged to research available clinical trials online using the websites along the bottom of page 5. If your doctor does not talk to you about clinical trials, raise the topic yourself. You deserve to know all the potential treatment options available.

MYTH The cost of care in a clinical trial is not covered by health insurance.

FACT Patient care costs (such as going to the doctor, hospital stays or certain testing procedures) may be covered by insurance. Although insurance does not typically cover research costs directly related to the study, it is common – although not guaranteed – for the trial sponsor to cover these research costs. Any questions you have about coverage should be asked and answered before you enter into a clinical trial.

MYTH Clinical trials are only for people who have no other options for treatment (a “last resort”).

FACT Clinical trials of cancer treatment may be available for individuals with cancer of all types and stages.

MYTH Clinical trials only take place at large hospitals or cancer centers.

FACT Many clinical trials take place at local hospitals, cancer centers and doctors’ offices. Clinical trials occur in all parts of the country, in both rural and urban areas.

MYTH Signing the Informed Consent form “locks” you into staying in a trial.

FACT You are free to change your mind at any time, even after signing the Informed Consent form. You can drop out of a trial at any time for any reason.

NATIONAL RESEARCH ACT

The National Research Act was passed into law in 1974. This act, which outlines the safety for participants of clinical trials, identifies three basic ethical guidelines that should be followed when conducting biomedical and behavioral research involving humans.

1 RESPECT FOR PEOPLE – All humans, including people who require assistance to make their own decisions, should be respected and have the right to choose what treatments they receive.

2 BENEFICENCE – People are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by 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 benefit and burdens of research.

FACT Clinical trials of cancer treatment may be available for individuals with cancer of all types and stages.
As you consider whether to join a clinical trial, it is important to think about the costs. When you explore your plan benefits with your insurance company, you may be pleasantly surprised to learn you can have access to innovative treatment and be an integral part of cancer research without incurring a great deal of additional expense. You also, however, don’t want to be surprised about any unexpected fees after the fact. Be sure to research your financial responsibility in the trial before beginning it. The expenses surrounding each clinical trial differ for many reasons, such as the specific treatment used in the trial, the trial organizer’s ability to cover some or all of the costs, and your insurance benefits. Although the cost of healthcare is an ongoing concern, you are encouraged not to dismiss a clinical trial as a treatment option until you’ve explored the financial resources that may be available to help.

Routine patient care costs typically include those related to doctor visits, hospital stays and some testing procedures. These costs are part of standard care, which would be included in a clinical trial and in standard treatment. Routine care costs are most times covered by your insurance during a clinical trial. Research costs, which are directly related to the clinical trial and include drugs and procedures, are typically covered by the trial sponsor.

A detailed list of the costs covered by the trial and those you or your insurance policy cover will be included in the informed consent form you must sign to participate in a trial. Before you sign the consent form, it is extremely important to address all of your cost and payment questions and concerns. Make sure this section also clarifies services not covered but recommended as part of follow-up and ongoing care. This clarification will help identify things that are likely not covered by your plan. For example, your insurance company may not consider follow-up tests and imaging studies done solely for data collection and analysis as part of routine patient-care costs. Be sure to discuss costs with the clinical trial administrators and contact your insurance company for an explanation of coverage.

Additionally, it’s important to check into federal and state requirements associated with clinical trials. Government programs may be available to assist. Some federal programs, for example, help pay the costs of care for clinical trial participants.

- Medicare covers portions of clinical research studies, such as trials designed to evaluate how well a cancer drug works. Medicare Part A and/or Medicare Part B may cover some things, such as office visits and tests, in certain qualifying clinical research studies. Talk with your medical team before proceeding to ensure you understand their recommendations, the costs and whether Medicare will cover the expenses.

- TRICARE is the Department of Defense’s health care program. In partnership with the National Cancer Institute (NCI), the Department of Defense now offers participation in Phase I, II and III NCI-sponsored cancer clinical trials as a TRICARE benefit.

- The Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored clinical trials at VA medical centers. All phases and types of NCI-sponsored trials are included.

The terms used to describe clinical trials and your medical insurance coverage can be confusing. Here are several key words and definitions that will help you communicate better about these topics with your health care team.

- Blinded: A study in which the participants do not know which treatment group they are in. In a single-blind trial, the participants don’t know what treatment they’re receiving. In a double-blind trial, neither the participants nor the researchers know who is receiving the drug being tested.

- Claim: A request for payment based on the terms of your insurance policy.

- Co-insurance: The percentage of medical care that you are financially responsible for paying after meeting your deductible.

- Control group: The participants who are assigned to receive the standard of care treatment that is being compared with one or more treatments being tested.

- Copay: The fixed amount you must pay for specific types of medical care, usually at time of service.

- Deductible: The amount of money you must pay before your insurance begins paying.

- Eligibility criteria: The guidelines defining who can participate in the clinical trial, based on factors such as age, sex, health status, and type and stage of cancer.

- Enrollment: The number of participants in a clinical study. The “estimated enrollment” is the number of participants that the researchers need for the study.

- Explanation of benefits (EOB): A statement provided by your health insurance company explaining what medical treatments and/or services were paid on your behalf.

- Informed Consent: A document that contains all the important information about the study, including the possible benefits and risks and the alternatives to the research being conducted. The document stresses that enrolling and remaining in the study are completely voluntary and that a person may leave the study at any time. Generally, it is required to sign an informed consent document to enroll in a clinical study.

- Intervention: A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Non-invasive approaches, such as surveys, education and interviews, can also be included.

- Out-of-pocket costs: Expenses for medical care that aren’t reimbursed by insurance and that you are responsible for paying. These costs may include deductibles, coinsurance and copayments for covered services, plus all costs for services that aren’t covered.

- Placebo: An inactive drug given in a control group to simulate treatment with an active agent. Placebos are not used in place of treatment in cancer clinical trials. They are given along with the standard treatment.

- Premium: The amount you pay each month to keep yourself insured.

- Protocol: The set of rules that every participating clinic, hospital, university or cancer center must follow in a clinical trial. The protocol outlines the eligibility criteria, specifies the tests that will be used and procedures that will be performed, and describes the medications and their doses, and establishes the length of each study.

- Recruitment: Indicates the current stage of a clinical study and whether it is or will be open for enrollment.

- Reimbursement: Compensation or repayment from your insurance company for health care services that you paid for out-of-pocket.

- Sponsor (lead): The sponsor is the organization or person (see also Sponsor-investigator) who oversees the clinical study and is responsible for analyzing the study data.

- Sponsor-investigator: The person who both initiates and conducts the clinical study.

- Standard of care: The drug or treatment that experts agree is the most widely used and appropriate therapy for a particular type and stage of cancer. In a Phase III trial, the standard of care drug or treatment is used as a baseline against which the drug or treatment being tested is compared.
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 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
- Study-specific treatment requirements:
  - Must have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) or Double Refractory to a PI and an IMiD
  OR
  - Prior treatment with at least one, but no more than three, lines of therapy for Multiple Myeloma, but not Refractory to a PI
- Other criteria apply

For more information ask your doctor about this study or visit www.clinicaltrials.gov (NCT# 03314181) to see if you qualify.