

Understanding Clinical Trials for Blood Cancers

Blood Cancer Treatment Series

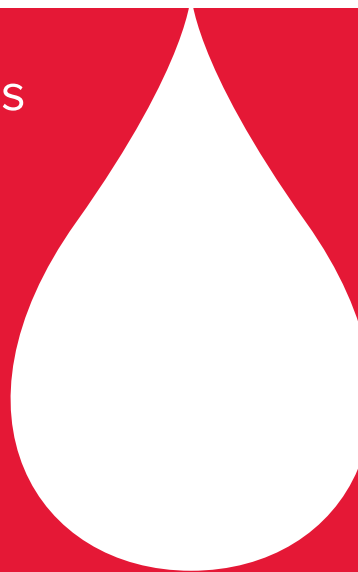


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Acknowledgement

The Leukemia & Lymphoma Society (LLS) gratefully acknowledges for her critical review and important contributions to the material presented in this publication,

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This publication is designed to provide accurate and authoritative information about the subject matter covered. It is distributed as a public service by LLS, with the understanding that LLS is not engaged in rendering medical or other professional services.

Introduction

A cancer clinical trial is a carefully controlled research study conducted by doctors to improve the care and treatment of cancer patients. A treatment that is proven safe and effective in a cancer clinical trial is often approved by the US Food and Drug Administration (FDA) for use as a standard treatment if it is more effective or has fewer side effects than the current standard treatment.

The purpose of clinical trials for the treatment of leukemia, lymphoma, myeloma, myelodysplastic syndromes, myeloproliferative neoplasms or other blood cancers is to improve treatment options, increase survival and improve quality of life. Advances in treatment for these blood cancers depend on clinical trials of new therapies or new combinations of therapies. A vivid example of this is the progress made treating children with acute lymphoblastic leukemia, the most common form of childhood leukemia. In 1966, the survival rate for these children was only 14 percent. Today, as a result of successful treatments made possible by clinical trials, more than 90 percent of children younger than age five years survive this form of leukemia.

As a result of studies in clinical trials, new therapies have been developed and approved for leukemia, myelodysplastic syndromes, myeloma, lymphoma and other blood cancers. To read more about specific therapies, see “About Blood Cancer Therapy” in the free LLS publication *Facts 2012*.

This booklet will help you to know more about how new treatments are developed, how clinical trials help advance blood cancer treatment, how to evaluate the benefits and risks of a clinical trial for yourself, what questions to ask to decide if a clinical trial is right for you and how The Leukemia & Lymphoma Society (LLS) can help.

Here to Help

The information in this booklet will be helpful when you talk to your doctor about clinical trials. We encourage you to take the lead in asking questions and discussing your fears and concerns. This will give members of your healthcare team the opportunity to answer your questions, extend emotional support and provide any needed referrals.

LLS Has Ways to Help. LLS offers free information and patient services for individuals and families touched by blood cancers.

Speak to an Information Specialist. Information Specialists are master's level oncology professionals. They provide accurate, up-to-date disease and treatment information and are available to speak with callers Monday through Friday, from 9 a.m. to 6 p.m. ET at (800) 955-4572. You can email infocenter@LLS.org or chat live with a Specialist at www.LLS.org.

Clinical Trials. Our Information Specialists help patients work with their doctors to find out about specific clinical trials. Information Specialists conduct clinical-trial searches for patients, family members and healthcare professionals. You can also use TrialCheck®, an online clinical-trial search service supported by LLS that offers patients and caregivers immediate access to listings of blood cancer clinical trials. Please see www.LLS.org/clinicaltrials.

Language Services. Free language services are available when you speak with an Information Specialist. Let your doctor know if you want a professional healthcare interpreter who speaks your native language or uses sign language to be present during your visit. Many times, this is a free service.

Free Materials. LLS publishes many free education and support materials for patients and healthcare professionals. PDF files can be either read online or downloaded. Free print versions can be ordered. Visit www.LLS.org/resourcecenter.

Información en Español. LLS has a number of resources available in Spanish for patients, caregivers and healthcare professionals. You can read and download these resources online at www.LLS.org/espanol or order printed copies by mail or by phone.

Other Helpful Organizations. Our website, www.LLS.org/resourcedirectory, offers an extensive list of resources for patients and families about financial assistance, counseling, transportation, summer camps and other needs.

Co-Pay Assistance Program. This program offers assistance for financially eligible patients with certain blood cancer diagnoses to help pay for private or public health insurance premiums and/or co-pay costs for prescription medications. Check www.LLS.org/copay or call (877) 557-2672 to speak to a *Co-Pay Assistance Program* specialist for more eligibility information.

Chapter Programs and Services. LLS chapter offices around the United States and Canada offer support and education. Your chapter can arrange for peer-to-peer support through the *Patti Robinson Kaufmann First Connection Program*. The *Patient Financial Aid* program offers a limited amount of financial aid for qualified patients. Find your chapter by calling (800) 955-4572 or by visiting www.LLS.org/chapterfind.

Telephone/Web Education Programs. LLS provides a number of free, live telephone and web education programs presented by experts for patients, caregivers and healthcare professionals. For more information, visit www.LLS.org/programs.

Reach Out. You and your loved ones can reach out for support in several ways. For example:

- LLS offers online Blood Cancer Discussion Boards as well as online chats at www.LLS.org/getinfo.
- Local or Internet support groups and blogs can provide forums for support.
- Patients with cancer often become acquainted with one another, and these friendships provide support.

Information for Veterans. Veterans with certain blood cancer diagnoses who were exposed to Agent Orange while serving in Vietnam may be able to get help from the United States Department of Veterans Affairs. For more information call the Department of Veterans Affairs at (800) 749-8387 or visit www.publichealth.va.gov/exposures/agentorange.

Depression. Treatment for depression has proven benefits for people living with cancer. Depression is an illness that should be treated even when a person is undergoing cancer treatment. Seek medical advice if your mood does not improve over time—for example, if you feel depressed every day for a two-week period. Contact LLS or ask your healthcare team for guidance and referrals to other sources of help, such as counseling services or community programs. For more information you can contact the National Institute of Mental Health (NIMH) at www.nimh.nih.gov and enter “depression” in the search box at the top of the web page, or call the NIMH toll-free at (866) 615-6464.

We’d Like to Hear From You. We hope this booklet helps you. Please tell us what you think at www.LLS.org/publicationfeedback. Click on “LLS Disease & Treatment Publications—Survey for Patients, Family and Friends.”

Talk with Your Doctor

Throughout this booklet we will continually mention how important it is for you to discuss clinical trial options with your doctor.

When you discuss treatment options with your doctor, it may be helpful to have

- A list of questions to ask (see the questions in Table 5, page 18 and download question guides at www.LLS.org/whattoask)
- A family member, friend or another advocate with you for support and to take notes.

You may want to give your doctor copies of information you find on treatment options, including cancer clinical trials, before you sit down to talk about your treatment plan. When you discuss your plan, don’t be afraid to ask the doctor to repeat information or to explain anything you don’t understand.

Getting another opinion from an expert about your diagnosis and treatment may be helpful in finding additional clinical trial options. There are thousands of clinical trials today for leukemia, lymphoma, myeloma, myelodysplastic syndromes, myeloproliferative neoplasms and other blood cancers. The trials are designed to improve treatment response rates and overall survival, reduce disease and treatment side effects, and provide a better understanding of each disease. By participating in clinical trials, doctors and patients together are unlocking the mysteries of these diseases and building new bridges to improved outcomes and quality of life.

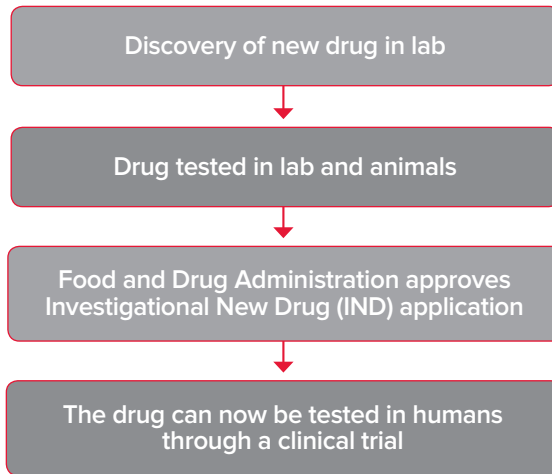
How Is a Clinical Trial Planned and Organized?

There are different types of cancer clinical trials. They are designed to develop and test new and improved ways to

- Diagnose and treat cancer in people
- Prevent or relieve treatment side effects
- Help prevent a return of cancer
- Improve comfort and quality of life for people with cancer.

Before a clinical trial begins, a new therapy is often developed and tested in a laboratory. Then it is thoroughly tested in animals. If the early research (the preclinical trials) shows the therapy is safe and effective, a carefully planned and monitored clinical trial of the drug or treatment will then be conducted in people (see page 5).

New Drug Development



A cancer clinical trial is developed and led by experienced doctors who specialize in cancer research. They decide on

- The disease to be treated
- The treatment that will be tested
- The goal(s) of the study (sometimes called “end points”)
- The type of patient who will be an appropriate participant in the study
- Ways to protect the participant’s safety
- How much medicine or other treatment will be given to patients in the trial
- How long the treatment will be studied in the trial.

Some cancer clinical trials are funded by an institution, such as the National Cancer Institute. Others are funded by organizations or companies — pharmaceutical companies, for example. A trial may take place at just a few specific locations or it may be conducted from many different venues across the United States or the world. In many cases, participants can get their treatments at various locations, which may include a large cancer center, a university hospital, a clinic, a local medical center or the physician’s office.

A cancer clinical trial is divided into four parts, called “phases,” each with a specific purpose (see Table 1, page 6). When each phase has been successfully completed the trial can move into the next phase.

Table 1. Phases of Clinical Trials

Phase 1

Treatment is tested in a very small group of patients to determine

- Its safety
- The appropriate dose (amount)
- The best way of giving the treatment.

Researchers watch patients closely for possible side effects of the treatment.

Phase 2

Treatment is tested in a larger group of patients to determine

- Whether the treatment works
- How well the treatment works.

Researchers will also continue to monitor patient safety in phase 2 and throughout the trial.

Phase 3

If the results of phase 2 studies are positive, the trial will move into phase 3.

Phase 3 trials are “randomized.” This means a “treatment group” is compared to a “control group.”

In a randomized trial

- The treatment group is made up of large numbers of patients who receive the “study” treatment.
- The control group is made up of large numbers of patients who are being treated with the best standard treatment.
- The outcomes of the treatment for the two groups are compared at specific time intervals.

The US Food and Drug Administration (FDA) will approve a treatment if it “passes” phase 3 testing—including meeting safety requirements—and is

- More effective than standard treatment
- Equally effective as standard treatment but has less toxic side effects.

Phase 4

At this phase in its development, the treatment in the study has already been approved by the FDA. Phase 4 studies are often performed to

- Identify an additional use for an already approved drug or other treatment
- Gather additional safety and effectiveness information from a larger group of patients
- Establish effectiveness in a subgroup of patients, for example, patients over age 65.

In some phase 3 and phase 4 randomized studies, the patients and the healthcare providers are told what treatment is being administered as part of the study protocol. Sometimes randomized phase 3 or phase 4 clinical trials are designed to be “single-blind” or “double-blind” studies. These strategies help ensure that the results of the study are without bias. In a single-blind study the patients do not know whether they are receiving the “study” treatment or the “standard treatment.” In a double-blind study neither the patients nor the clinicians (doctors and/or nurses) treating the patients know which participants are receiving which treatment. To ensure anonymity, the medications for double-blind studies are prepared and coded by researchers who are not giving the treatment to patients in the study.

What Is It Like to be Treated in a Clinical Trial?

Most clinical trials provide treatments for a designated disease, such as follicular lymphoma or a specific condition, for example, treatment-related fatigue. But trials do not include the extended or complete health care that would be routinely covered by your health plan. Your regular healthcare provider will work with the research team and make sure that the other ongoing medications or treatments you need will not interfere with the study treatment.

The clinical trial team is made up of doctors and nurses as well as social workers and other healthcare professionals. These clinicians check the health of each participant at the beginning of the trial, give specific instructions for taking part in the trial, monitor the health of each participant throughout the trial and, in some cases, they may stay in touch with patients after the trial is over.

Treatment in a clinical trial may be different from standard treatment in the following ways:

- Your responses to treatment will be followed closely in a study. You may receive more tests during treatment and have more doctors’ visits as part of the clinical trial than you would in your standard care setting.
- Treatment routinely covered by your health insurance or managed care plan may no longer be covered for patients enrolled in clinical trials. In some plans, coverage for patients who are receiving treatment as part of a clinical trial is set up differently (see pages 15 and 16).
- You may not know if you are receiving the study treatment or the best standard treatment. This is because many cancer clinical trials compare two patient groups (see the discussion of “randomized” drug trials in Table 1, phase 3 on page 6). However, federal regulations require patients to be told if a placebo (a substance that looks the same as the one used in the treatment but is inactive) will be used in a trial. Placebos are not typically used with patients in cancer clinical trials.

Are Clinical Trials Safe?

US clinical trials are designed to give patients the safest, potentially most effective clinical therapies. The trials are conducted once researchers have shown in the laboratory and in animal research that a particular study treatment has a good chance of offering better outcomes for people with a specific disease.

All trials follow strict scientific and ethical principles. Every clinical trial has an action plan, called a “protocol.” The same plan is used by every doctor at each treatment center taking part in the trial.

The plan or protocol specifies

- The purpose of the study
- The number of people who will be recruited for the study
- The group of patients eligible to participate in the study (e.g., patients with a particular type of blood cancer, meeting general health requirements)
- Any agents (treatments) participants will receive, the dosage and how often
- The medical tests participants will be asked to undergo
- The number of visits that will be required for follow-up (either at the study location or with a local physician)
- The type of participant information that will be gathered
- The end points of the study.

An “end point” is the event or outcome of the study that researchers will be able to measure. It provides a way for them to evaluate the results of the “study” treatment. Research teams establish the end points of a trial before it begins. The end points for a given study depend on the type and phase of the clinical trial. Some examples of end points are response rates or time to progression of disease; toxicity (are there any harmful effects of the agent?); and quality of life (whether there are any treatment effects on overall enjoyment of life and sense of well-being).

There are several processes in place to ensure that trials are safe for patients (see Table 2, page 10). They provide oversight and monitor trial protocols to make certain that

- Study risks do not outweigh potential benefits
- Randomization of treatment groups is conducted fairly and ethically.

The Informed Consent Process. “Informed consent” is the name given to the ongoing interactive informational process that begins when a person first expresses

interest in a clinical trial. “Informed consent” is also the term for a document that provides detailed written information about the trial.

If you are considering participating in a clinical trial, the doctors and nurses involved in the trial will explain the study to help you decide if you want to take part. The patient, as well as key decision makers in the family, should be present. People who need the services of a language interpreter may request one.

The informed consent process gives you

- A chance to ask questions—both during your first meeting and then at follow-up meetings—so you have the information you need to make a decision.
- Time to review the details of the study; you will be given written information so that that you can take it home, read it over, and discuss it with your doctor, family or others you trust.
- What to expect in the study (tests, financial burdens, option to decline at any time).

You must agree to sign an informed consent document before you can begin the trial protocol. It affirms that you fully understand the nature of the study. It is not a contract, though, and you are free to leave the study if any new information leads you to want to do so. In fact, you may withdraw from the trial at any time, for any reason. If you do enter a study and then withdraw you should let the research team know your reasons for leaving the study.

The informed consent document includes

- Details about the study, such as its purpose and length (duration)
- Key contacts
- The examinations and lab tests that are needed with the treatment
- Study risks and potential benefits.

You can decide whether or not to sign the informed consent document after reading it. Take the time you need to think about it and discuss it with family members or caregivers. Be sure that you fully understand the information. Read the informed consent document very carefully and if you have questions and concerns, write them down. Take that list with you when you next meet with the physician or nurse. In that way, you will be sure to remember what issues you wanted to address and get answers to all your questions.

New information may become available to the research team as the trial goes along. The clinical trial study design (protocol) may also change over time. The informed consent process requires that members of the research team update you when there are such changes. You may also be asked to sign a new informed consent document.

Table 2. Safeguards in Clinical Trials

Oversight/monitoring provided by	Responsibility
Sponsoring organization The sponsoring organization seeks outside review of merits of the study.	The sponsoring organization provides for outside experts who will evaluate the purpose and design of the study. They will also determine if the study is of value and if it is possible, as designed, to conduct it safely in the setting(s) as described.
Study (principal) investigator The principal investigator supervises the treatment plan.	Prepares or follows an action plan for the study (protocol) that outlines how many people will take part in the study, what medical tests they will receive and how often, and the treatment plan. There may be many cooperative centers (participating institutions) in different locations offering the same clinical trial. The same protocol is used by each doctor who takes part in the study.
Institutional Review Board (IRB) The IRB reviews, monitors and approves the treatment plan.	Each participating institution has an IRB or uses a centralized IRB, made up of healthcare professionals, clergy members, community leaders and other community members. The IRB <ul style="list-style-type: none">○ Reviews the plan to make sure the study is conducted fairly and participants are not likely to be harmed○ Decides how often to review the trial once it has begun. Based on this information, the IRB decides whether the clinical trial should continue as initially planned and, if not, what changes should be made○ Can stop a clinical trial if the researcher is not following the protocol or if the trial appears to be causing unexpected harm○ Can also stop a clinical trial if there is clear evidence that the new intervention is effective, in order to initiate steps to make it widely available.

Table 2. Safeguards in Clinical Trials (contd)

**Oversight/monitoring
provided by**

**Data Safety Monitoring
Board (DSMB)**

The DSMB monitors
all trial results.

Responsibility

The DSMB is an independent committee made
up of statisticians, physicians and other expert
scientists.

The DSMB

- Periodically monitors the results, tests, and
safety of some phase 1 and phase 2 trials
and all phase 3 trials to ensure that the risks
of participation are as small as possible
- Makes sure the data are complete
- Monitors all trial results; if early results
show clear advantages of a new drug,
the DSMB can recommend that the
trial should end early to move on to the
approval process more quickly. The DSMB
might recommend that a trial should end
early if there is compelling evidence that the
new treatment is not working or that it has
severe or life-threatening side effects.

Who Can Participate in a Cancer Clinical Trial?

Your doctor may speak to you about being treated in a clinical trial. However many patients seen by a hematologist or oncologist say that their specialists never informed them about the possibility of participating in a trial. Blood cancer patients or their advocates need to ask their doctors about clinical trials.

Some people may think they should wait until standard treatment fails before considering a clinical trial. However, clinical trials are not only for people with the most advanced disease. A trial can be designed to test new treatment(s) that improve response rates or improve the quality of life of patients with newly diagnosed or very limited disease.

Clinical trials are appropriate for different types of people depending on the purpose and phase of the trial. Study researchers develop patient eligibility criteria which may include

- Disease type
- Patient age/gender/race
- Stage of disease
- Other treatments used by the patient
- The presence of any other illnesses or conditions.

Some trials might require that you try standard treatment first; other trials may be for patients who have not had any previous treatment. Some trials may require you to allow a period of time before switching from a standard treatment to a study treatment. Some trials exclude patients with illnesses such as liver or kidney disease because the study uses treatments that put stress on these body parts.

Some patients may be concerned about participating in a clinical trial because of

- Fear of getting less than standard care
- Language barriers or cultural differences
- Treatment-related expenses
- Lack of access to trials at a clinic/institution
- Family/work responsibilities.

If you are interested in a clinical trial but are concerned about any of these things, speak to the doctor or nurse on the clinical trial team. He or she will answer any questions you have and discuss your concerns.

How to Find Cancer Clinical Trials that Might Be Right for You

- Begin by talking with your doctor about participating in a clinical trial as a treatment option.
- Contact our Information Specialists who can help you to identify the information you will need about your diagnosis and treatment history to determine for which trials you might be eligible. Information Specialists can also conduct clinical-trial searches and help you to develop a list of questions to ask your current doctor or the trial team about participating in a trial. Patients,

family members and caregivers can also use TrialCheck®, an online clinical-trial search service supported by LLS that offers immediate access to listings of blood cancer clinical trials. Please see www.LLS.org/clinicaltrials.

- You may want to gather information from the Internet or from organizations and advocacy groups.
- Once you and/or your doctor conclude that participating in a clinical trial might be a good option for you, ask your doctor or another member of your healthcare team to contact the clinical trial team on your behalf. This is because the trial team will ask many questions related to your medical and treatment history to determine if the clinical trial is right for you.
- If you find out about a trial that is of interest to you and your current doctor cannot make the inquiries for you, you may want to contact the trial team directly. Ask to speak with the “trial coordinator,” the “referral coordinator,” or the “protocol assistant.” This information can be found on the protocol summary. The trial coordinator answers questions from potential patients and their doctors and will make a preliminary assessment of your eligibility for the trial. A final determination will be made after an initial appointment. You may want to contact our Information Specialists first, as they can assist you with the basic information you need to contact the trial team.
- There are many types of treatments offered through cancer clinical trials for leukemia, lymphoma, myeloma, myelodysplastic syndromes, myeloproliferative disorders and other blood cancers (see Table 3).

Table 3. Types of Studies

Treatments	Study Questions
Drug therapy New chemotherapy drugs or new combination of drugs are tested.	What is the best order and combination of chemotherapy drug therapies?
Drug maintenance therapy Therapy with a drug, or combination of drugs, to maintain a remission is tested.	Is disease progression or overall survival any different with or without maintenance therapy?
Targeted drug therapy Drugs designed to destroy specific cancer cells continue to be investigated.	Does the targeted therapy used alone have better response rates and/or overall survival but fewer side effects than standard therapy? Should it be combined with other standard therapies to improve effectiveness?

(continued on next page)

Table 3. Types of Studies (contd)

Treatments	Study Questions
Radiation therapy New combinations of treatment types are being investigated.	Are outcomes improved compared to current outcomes for patients getting combined radiation and drug therapy?
Immunotherapy Immunotherapy (to trigger the body's immune system to fight cancer cells) is being studied.	If there is a good response, should the therapy be combined with standard treatment or used alone?
Radioimmunotherapy Radiation delivered to blood cancer cells by attaching a radioisotope to a monoclonal antibody (highly specific antibodies that can be produced in the laboratory and used for targeted delivery of drugs to cancer cells), continues to be investigated.	Approved by the FDA for relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin lymphoma, can this treatment be used as a first-line therapy with fewer side effects and with equal or better overall survival time than current standard front-line treatment options?
Stem cell transplantation New stem cell transplantation procedures are being studied for many forms of blood cancer.	When is the best time for stem cell transplantation and which type of transplant is best (auto, allo, "mini", tandem)?
Supportive therapy Treatments to reduce symptoms or treatment-related side effects such as nausea, vomiting, infection or fatigue continue to be studied.	Does the supportive therapy reduce side effects and improve patients' quality of life? Does it interfere with or compromise the effects of cancer therapy?
Disease and treatment response monitoring Diagnostics and monitoring techniques continue to be investigated.	Are certain cytogenetic tests good indicators of the likelihood of progression of an indolent disease such as chronic lymphocytic leukemia or myeloma? How do imaging technologies such as MRI and PET scans compare in evaluating responses to therapy and recurrence of lymphoma and other blood cancers?

The Leukemia & Lymphoma Society's Information Specialists can assist you and your healthcare provider with clinical-trial searches that take into account your disease, treatment history and where you live. Please call our Information Specialists at (800) 955-4572 or visit our website at www.LLS.org/clinicaltrials.

Remember that each person's situation is different. It's important to ask your doctor about whether a study treatment might be a good choice for you.

What You Need to Know and Do Before You Decide

Once you have found a clinical trial you might want to join, you will be faced with some important considerations. You will need to know how your care will be paid for and how your participation in a trial will impact your usual treatments and day-to-day life for you and members of your family.

Costs, Insurance and Medicare Coverage. Some costs of a clinical trial may be covered by the sponsor of the study. Most studies provide the drug or treatment free of charge.

Other costs may or may not be covered by health insurance plans. It is important to speak to the clinical trial sponsor and your insurance provider to learn ahead of time what will be covered. There are steps that you can take to find out about your coverage. Insurance reimbursement varies depending on the treatment, the insurance company and the health insurance policy.

Ask if your treatment costs are expected to be covered by the clinical trial sponsor, your insurance provider or by you. Even if you are insured, some of the costs may not be covered.

In general, costs that are covered or are provided free of charge by the study sponsor are the

- Research doctor's and nurse's time
- Cost of drug being studied.

There are certain routine patient care costs that you would be responsible for whether or not you were participating in a clinical trial; these costs may or may not be covered by the sponsor or by your insurance. These routine costs include

- Doctor's visits
- Hospitalizations
- Laboratory tests
- Procedures (such as bone marrow biopsies or lymph node biopsies)
- Radiology tests
- Routine medical care
- Drugs that are not part of the study design.

Many types of new cancer treatments can be tolerated by older patients as well as younger patients. Medicare pays for routine care costs (such as office visits and regular medical tests) for people enrolled in federally funded clinical trials. Information about this coverage is available online at www.cms.hhs.gov/ClinicalTrialPolicies or you can call the Centers for Medicare and Medicaid Services at (800) 633-4227.

LLS is advocating for increased patient access to cancer clinical trials on the state level including routine patient care costs. Lack of access to insurance coverage for routine patient care is cited as one of the leading causes of low adult participation in clinical trials, which is only 3 to 5 percent nationally.

A growing number of states have addressed this key issue and more are expected to follow. Visit the National Cancer Institute's website "States That Require Health Plans to Cover Patient Care Costs in Clinical Trials" at www.cancer.gov/clinicaltrials/payingfor/laws, to see if your state has legislation and what routine care the bill covers.

To get more information:

- Talk with your doctor, nurse, social worker or the study contact person to find out if the study drug is offered free of charge or at low cost from the drug company.
- Your healthcare providers and your insurance representative can tell you the expenses that are covered by your health insurance plan.
- If your health insurance company will not pay treatment costs or denies your claims, you or your healthcare provider can contact other groups including drug manufacturers or advocacy groups for assistance. Organizations that may have information and suggestions to help you appeal denied insurance claims include The National Coalition for Cancer Survivorship (877) 622-7937 and The Patient Advocate Foundation (800) 532-5274. You can also visit www.LLS.org/resourcedirectory for additional organizations that may be able to help.
- Your own doctor or the research study contact can send necessary information to your insurance company about the benefits of the study treatment for you and if they think it might be helpful, they can point out to your insurance provider that other companies have paid for such treatment. You may have to provide more information once the study begins.

How Participation in a Trial May Affect You and Your Family. You may be considering all treatment opportunities, including clinical trials, before making a choice about the treatment that is right for you. Or you may be looking for a cancer clinical trial if standard treatment is not working. Together you and your doctor can decide if and when a clinical trial is right for you.

You and your doctor can discuss

- Your individual situation
- Your type of disease
- Any treatment you may have had so far
- The cancer clinical trials for which you might be eligible.

There are pros and cons to participating in a clinical trial (see Table 4). It is important to review these and make them part of your discussion with your doctor.

Table 4. Pros and Cons of Participating in a Clinical Trial

Pros	Cons
Treatment choice You will receive high-quality care, receiving either the study treatment or best standard treatment.	If you are participating in a phase 3 study and it is randomized into treatment groups, you may not be able to choose which therapy you receive.
Uncertainty of side effects or response You will gain access to new research treatments before they are widely available.	Potential side effects of the study treatment may be unknown; there may be unpleasant, serious or even life-threatening side effects to treatment. Or, there might be fewer side effects with the study treatment but it is not yet known if it is as effective in treating the disease as the standard treatment.
Costs involved In some cases, the manufacturer of the study drug may pay for some or all of the costs of the study treatment.	Your insurance policy may or may not pay all, part, or any of the costs of the study.
Time requirement You will be monitored very carefully during the study period and may receive expert follow-up after the study is completed.	The study protocol may require more of your time and attention than would a nonprotocol treatment. It is likely to require trips to the study site, possible hospital stays or complex dosage requirements.

Table 5. Questions to Ask Your Doctor

Treatment Option Questions

- What are my treatment options right now? What is the goal of the treatment?
- What are the advantages, disadvantages, and side effects of my current (or standard) treatment?
- Will I be able to take my regular medications?
- Are there any clinical trials for which I might be eligible?
- How would the study treatment be different from the standard treatment?
- What kind of tests would I receive? What are the expected side effects of the study treatment versus the standard treatment?
- How long will I be treated in the study?
- What is the purpose of the study and why do researchers think the approach may be effective?
- Who will be in charge of my care and where will I be treated?
- How and when will I know if my treatment is or isn't working?
- Will my treatment options change if the current treatment doesn't work?
- If not now, when and under what circumstances would a clinical trial be an option for me?

Clinical Trial Questions

- How will I find out about clinical trials that might help me?
- Are there clinical trials available where I'm being treated now, or would I need to change treatment locations?
- How do I know whether my insurance will cover the costs of the clinical trial? Will I have to pay for any part of the trial such as tests or the study drug?
- Who can help answer any questions from my insurance company or health plan?
- Can I talk to other people in the study?
- Will there be any travel or child care costs that I need to consider while I am in the trial?
- How will I know if the study treatment is working for me? Will general results of the trials be provided to me?
- Will I have responsibilities such as keeping a log or filling out forms about my health?
- Will the study team continue to check on me after the treatment is over?

More Information

Free LLS publications include

*Knowing All Your Treatment Options/
Conozca todas sus opciones de tratamiento*

Resources

Centers for Medicare and Medicaid Services (CMS)
www.cms.hhs.gov/ClinicalTrialPolicies
(800) 633-4227

CenterWatch
Clinical Trials Listing Service
www.centerwatch.com

ClinicalTrials.gov
Information on Clinical Trials and Human Research Studies
www.clinicaltrials.gov

CureSearch for Children's Cancer
CureSearch Children's Oncology Group
www.curesearch.org
(800) 458-6223


Food and Drug Administration (FDA)
www.fda.gov
(888) INFO-FDA or (888) 463 6332

National Cancer Institute (NCI)
www.cancer.gov/clinicaltrials
(800) 4-CANCER or (800) 422 6237

National Coalition for Cancer Survivorship (NCCS)
www.canceradvocacy.org
(877) 622-7937

Patient Advocate Foundation (PAF)
www.patientadvocate.org
(800) 532-5274

Notes



LEUKEMIA &
LYMPHOMA
SOCIETY®

LIGHT THE
NIGHT® WALK

*The Leukemia & Lymphoma Society's
Light The Night Walk*

Taking Steps to Cure Cancer™

Join a Light The Night Walk near you to
raise funds for lifesaving cancer research
and to improve patients' quality of life.



LIGHTTHENIGHT.ORG ★ 877.LTN.WALK

REACH OUT TO OUR **INFORMATION SPECIALISTS**

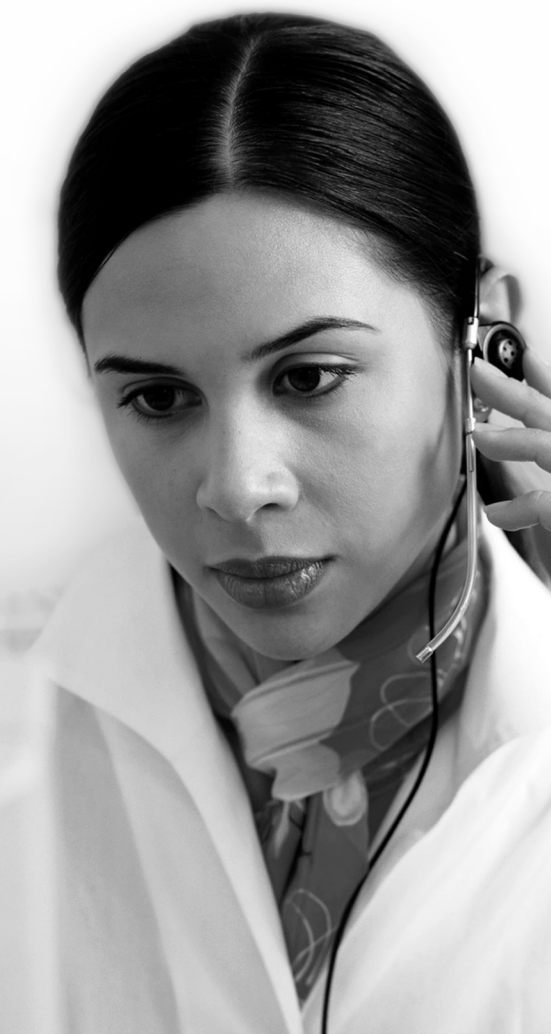
The Leukemia & Lymphoma Society's (LLS) Information Specialists provide patients, families and healthcare professionals with the latest information on leukemia, lymphoma and myeloma.

Our team consists of master's level oncology professionals who are available by phone Monday through Friday, 9 am to 6 pm (ET).

Co-Pay Assistance

LLS's Co-Pay Assistance Program helps blood cancer patients cover the costs of private and public health insurance premiums, including Medicare and Medicaid, and co-pay obligations. Support for this program is based on the availability of funds by disease.

**For more information,
call 877.557.2672 or
visit www.LLS.org/copay.**

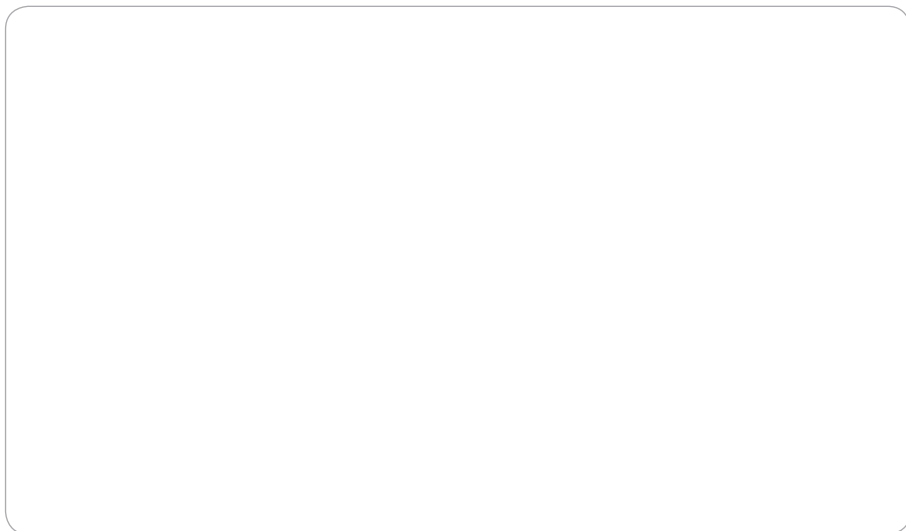


For a complete directory of our patient services programs, contact us at

800.955.4572 or www.LLS.org

(Callers may request a language interpreter.)

For more information, please contact:



or:

National Office

1311 Mamaroneck Avenue, Suite 310, White Plains, NY 10605

Contact our Information Specialists **800.955.4572** (*Language interpreters available upon request*)

www.LLS.org

Our Mission:

Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

LLS is a nonprofit organization that relies on the generosity of individual, foundation and corporate contributions to advance its mission.