



CANCERcare
Connect[®]

Clinical Trials: Improving the Care of People Living With Cancer

Presented by

Mary McCabe, RN, MA

Memorial Sloan-Kettering Cancer Center

Carolyn Messner, DSW

CancerCare

Learn about:

- Stages of clinical trials
- Benefits of participating
- Questions to ask your doctor
- Your support team



CANCERcare[®]

Help and Hope



CANCER*care*[®]

CancerCare is a national nonprofit organization that provides free support services to anyone affected by cancer: people with cancer, caregivers, children, loved ones, and the bereaved. *CancerCare* programs—including counseling and support groups, education, financial assistance, and practical help—are provided by professional oncology social workers and are completely free of charge. Founded in 1944, *CancerCare* provided individual help to more than 100,000 people last year and had more than 1 million unique visitors to our websites. For more information, call 1-800-813-HOPE (4673) or visit www.cancercares.org.

Contacting *CancerCare*

National Office

CancerCare
275 Seventh Avenue
New York, NY 10001
Email: teled@cancercares.org

Administration

Tel: 212-712-8400
Fax: 212-712-8495
Email: info@cancercares.org
Website: www.cancercares.org

Services

Tel: 212-712-8080
1-800-813-HOPE (4673)

If you are a health care professional interested in ordering free copies of this booklet for your patients, please use the online order form on our website, www.cancercares.org.

Clinical Trials: Improving the Care of People Living With Cancer

Presented by

Mary McCabe, RN, MA

Director, Cancer Survivorship Program
Memorial Sloan-Kettering Cancer Center
New York, NY

Carolyn Messner, DSW

Director of Education & Training
CancerCare

The information in this booklet is based on the CancerCare Connect® Education Workshop “Clinical Trials: Improving the Care of People Living With Cancer.” The workshop was conducted by CancerCare in partnership with the American Society of Clinical Oncology, Intercultural Cancer Council, National Cancer Institute, National Coalition for Cancer Survivorship, Research Advocacy Network, and The Wellness Community.

INTRODUCTION

page 2

- HOW DO CLINICAL TRIALS WORK? *page 3*
- WHAT ARE THE BENEFITS OF JOINING A CLINICAL TRIAL? *page 6*
- AM I ELIGIBLE FOR A CLINICAL TRIAL? *page 7*
- WHAT RIGHTS AND PROTECTIONS DO I HAVE IN A CLINICAL TRIAL? *page 9*
- CANCERCARE® CAN HELP, *page 10*

FREQUENTLY ASKED QUESTIONS

page 12

RESOURCES

page 16

This patient booklet was made possible by a charitable contribution from Bristol-Myers Squibb.

Clinical trials are an important option in cancer care.

Cancer clinical trials are research studies that involve people with cancer. The goal of these studies is to find better ways to diagnose, treat, and prevent cancer so that people can live better and longer. The studies also give us more information about reducing cancer risk in healthy people.

Compared with the large number of children with cancer who take part in clinical trials, a very small number of adult patients do so—as few as three to five percent. So there is a



large effort to help people understand the importance and benefits of clinical trials. Researchers are also reaching out to include more members of minority groups and the elderly in clinical trials.

Treatment guidelines are developed from the results of clinical trials. Doctors across the country and around the world follow these guidelines so they can deliver the best possible treatment to their patients. Today there are about 12 million cancer survivors in the United States, mainly because of the work done in clinical trials. That is why it is so important to continue this research.

There are many reasons why people take part in clinical trials, but most hope they will help themselves today and others in the future. These volunteers are doing something very important to help future cancer patients.

How Do Clinical Trials Work?

A clinical trial often starts with a scientific idea based on results of laboratory research. Researchers who come up with these ideas may work in cancer centers, universities, community clinics, pharmaceutical company labs, or hospitals. Most funding for clinical trials comes from the government's National Cancer Institute and from the pharmaceutical industry. Together, doctors and researchers design the studies and how they will work.

Clinical trials that test new drugs or other treatments are done in phases. Each phase has a different purpose and helps researchers answer different questions. If a new drug or treatment does not seem promising in the early phases, the research can be stopped.

PHASES OF CLINICAL TRIALS

In **phase I trials**, researchers study the safety of a new drug or drug combination or a new dose. Phase I trials usually have only a small group of 15 to 30 people. This type of study looks at safety and any side effects that might occur with the treatment. In phase I trials, researchers try to find the smallest dose that will still be effective. They usually take place in research institutions, where patients can be closely monitored.

In **phase II trials**, the new drug or treatment is given to a larger group of people (but generally less than 100) to see if it is effective and to learn more about its safety. Like phase I studies, phase II trials are usually conducted at research institutions, such as large teaching hospitals and cancer centers. In some phase II studies, patients may be randomized. This means patients in the trial are selected by

chance to get either the new treatment being studied or one that is already being used. In order to avoid influencing the results, patients (and often their doctors) do not know which group they are in.

Randomized clinical trials are considered the most reliable way of determining which treatments work best.

In **phase III trials**, the study drug or treatment being tested is given to even larger groups of people (1,000 to 3,000). During this phase, researchers are able to:

- Confirm how well the treatment works
- Learn about side effects they might not have seen during earlier phases with smaller groups
- Compare the new treatment with currently used standard treatments
- Collect information that will allow the new drug or treatment to be used safely



In phase III trials, patients are randomized, as described above.

In cancer clinical trials, patients are generally not given a placebo (a look-alike pill or liquid that contains no active ingredient). A placebo is only used when there is no standard treatment against which a new treatment can be compared.

Phase III studies are often carried out in the community by local doctors in private practice, in community hospitals, or in special cancer centers. Because phase III trials involve large numbers of people, doctors can better understand how a treatment will work in people with many different health factors.

Types of Clinical Trials

Depending on the goals of the trial, there are several different types:

- **Prevention trials** look for better ways to reduce the risk of cancer in people who have never had it or to prevent the cancer from coming back. These approaches may include medicines, vitamins, vaccines, or lifestyle changes.
- **Screening trials** test the best way to detect cancer.
- **Diagnostic trials** try to find better tests or procedures for diagnosing a particular cancer.
- **Treatment trials** test new treatments, new combinations of drugs, new ways to deliver treatment, or new approaches to surgery or radiation.
- **Quality-of-life trials (or supportive care trials)** explore ways to improve comfort and the quality of life for people with cancer.

In **phase IV trials**, researchers study drugs after they have been approved by the U.S. Food and Drug Administration (FDA) and marketed to the public. Phase IV trials are designed to learn more about the treatment's risks and benefits and the best way to use it. These studies help doctors understand how safe and useful the treatment will be over the long term.

“PERSONALIZING” TREATMENT BASED ON A TUMOR’S GENETIC MAKEUP

Genes are the blueprint for each cell in the body, including tumor cells. They determine how that cell behaves. Sometimes, when a particular treatment is working well in some patients but not in others, researchers may discover that having—or not having—a certain gene or a variation in a gene may be the reason.

In a new approach to clinical trials, new participants joining the trial whose tumors have the same genetic makeup are more likely to receive the drug. This gets answers more quickly and requires fewer participants to find out whether a drug works.

What Are the Benefits of Joining a Clinical Trial?

Being in a clinical trial lets you play an active role in your health care. Your own cancer doctor will still care for you, but in a clinical trial you also receive:

■ **Close observation by cancer experts** Because a clinical trial must follow a strict protocol, or plan, people in clinical trials are very closely observed. This is the only way researchers can be sure that the information they get from the study is accurate and complete.

■ **Access to new cancer treatments and techniques**

(such as a better way of delivering treatment) before they are widely available.

Doctors perform clinical trials because they believe the drugs or techniques they are testing

could be more effective or safer than the treatments they're using now. But doctors also have to prove it scientifically.

Only with this proof will the FDA approve the new treatments or techniques for other people with the same cancers.



As with all medical treatments, there may be risks associated with the treatments used in clinical trials. These risks include side effects and the possibility that the new treatment may not work well for you. Before you agree to enter a study, your doctor or nurse will fully explain the possible risks and make sure you understand them.

Another thing to consider is that participating in a clinical trial may take up more of your time and attention than you expected. There may be trips to the hospital or clinic where the study is being done, hospital stays, or a complex schedule for taking medications. Always feel free to ask your health care team any questions you may have about the clinical trial.

Weighing the risks and benefits of a clinical trial is a very personal decision. There is no right or wrong answer. Only you can decide if a trial is right for you.

Am I Eligible for a Clinical Trial?

Not everyone will be accepted into every trial. When planning a clinical trial, researchers decide on the characteristics of the people they would like to study. Each trial has a different set of characteristics. Some common examples include:

- Age
- Cancer type and stage
- Treatments the person has already undergone
- Other medical concerns, such as diabetes or heart disease

If you think you would like to take part in a clinical trial, you can ask your doctor or nurse about the trials available for your cancer. You can also search online using the websites in our resource list on page 16. There are toll-free numbers available as well, so you can talk to someone who can guide you.

What Questions Should I Ask?

If you and your health care team have decided that a clinical trial is the right choice for you, you should have an honest discussion with them before you sign an informed consent form. There are a number of questions to ask, including:

- What is the purpose of the study?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this study affect my daily life?
- How many visits per week or month will I need to make?
- How long will the study last?
- Is a hospital stay required?
- Who will pay for the treatment? Will the trial, or my insurance, cover all or part of it?
- What will I need to pay for myself?
- Will I be reimbursed for any expenses such as transportation?
- What type of long-term follow-up care is part of this study?
- How will I know that the treatment being studied is working? Will the results of the trial be given to me?
- Who will be in charge of my care?
- Are there other experts I can talk to about this study?
- Can I take the informed consent form home to talk it over with my family or partner?



What Rights and Protections Do I Have in a Clinical Trial?

People who take part in clinical trials have both rights and protections to make sure their privacy and well-being are taken care of. One of the most important protections is called informed consent. This is a process to ensure that the participant understands all aspects of the study, including the risks and benefits. A written consent document is signed by a patient, stating that he or she has entered the trial of his or her own free will without being pressured. As a patient in a clinical trial, you must be able to follow study instructions, but you always have the right to leave a clinical trial at any time for any reason.

Besides informed consent, you will be asked to sign another form called a HIPAA Authorization. HIPAA stands for Health Insurance Portability and Accountability Act. This form allows doctors to use your health information as part of the report on the study, without using your name or other personal details.

Each research institution, hospital, or cancer center that conducts clinical trials has a committee called an Institutional Review Board (IRB). An IRB includes doctors, nurses, lawyers, and people like yourself. The IRB reviews each clinical trial to make sure it is safe and ethical, in order to protect the people who take part. They review the study on a regular basis to be sure it is being carried out properly.

If you have concerns about any part of being in a clinical trial, you may be able to speak with a patient representative at the institution where the trial is being conducted. The name and contact information for this person are usually included on the informed consent document. If a patient representative is not listed, ask if there is someone else you can speak with, such as a nurse or social worker, to answer any questions you might have.

CancerCare® Can Help

When you are being treated for cancer and are thinking about entering a clinical trial, you may have many concerns about the process. It's perfectly normal to feel confused or nervous about clinical trials. But the more you learn about what's involved and what to expect, the better you'll feel about your decision.

Help is available to you as you consider your options. Your health care team, family members, and friends will likely be your main source of support. CancerCare is also here to help. We offer the following free resources:



Counseling Often, when people are thinking about enrolling in a clinical trial, they need someone to talk with who will help them sort through the emotional and practical concerns that come up.

Oncology social workers provide emotional support, help you find ways to stick with treatment and cope with side effects, and guide you to resources. CancerCare offers free counseling from professional oncology social workers on staff.

Support groups Talking with other people who have taken part in clinical trials can help reduce the feeling that you are going through it alone. These groups provide reassurance, suggestions, insight—a safe and supportive place where people can share similar concerns. At CancerCare, people with cancer and their families take part in support groups in person, online, or on the telephone.

Connect® Education Workshops In these workshops, you can hear about the latest treatments and clinical trials directly from leading medical experts in one-hour presentations. You can listen live by telephone or you can download podcasts of past workshops from our website.

Publications Free booklets and fact sheets from CancerCare provide up-to-date, easy-to-read information about the latest on clinical trials, treatments, managing side effects, and coping with cancer.

Financial help For those who qualify, CancerCare can provide financial assistance to help with some costs that might arise during a clinical trial, such as transportation and child care. Social workers and case managers are knowledgeable about financial issues and will work closely with you to get you the help you need.

Referrals to resources CancerCare can help you learn about other organizations in your community and nationwide that can assist you in finding a clinical trial that is right for you.

To learn more about how we help, call **1-800-813-HOPE (4673)** or visit **www.cancercare.org**.

Frequently Asked Questions

Q **If I find a clinical trial online, can I just sign up, or do I have to go through my doctor?**

A At www.clinicaltrials.gov, for example, you may get in touch with the contact person listed, but you cannot sign up online. The National Institutes of Health, which operates this website, recommends that you talk with your doctor about the right clinical trial for you.

You should know that all clinical trials have guidelines about who can participate. These qualifications are used to:

- Identify the right patients for the trial.
- Keep all participants safe.
- Make sure that researchers will be able to answer the questions they plan to study.

Your doctor can advise you about whether you qualify for a study and help you contact the researchers involved.

Before you meet with your doctor for that discussion, do your homework by searching online or calling the toll-free numbers listed on page 16. Your doctor may not know about newer studies that are available for you. Some people with cancer have placed their names in databases for future clinical trials. If you let your doctor know that you would like to hear about new clinical trials, he or she can help you stay informed.

Q I'm in a clinical trial now and have experienced side effects from the drug I'm taking. Do the doctors need to stick with the plan of the clinical trial?

A All doctors in a clinical trial must follow protocols—that is, the plan for what treatment will be studied and how it will be given to patients. However, it is very important to let your health care team know about any side effects you are having. This is the only way they will be able to help you manage your symptoms so you can feel better. Knowing what side effects the drug causes is also important for research purposes. You are helping yourself and the researchers by being as honest as possible.

Q I live in a rural area. I can't convince my doctor to sign me up for a clinical trial. What should I do?

A Living in a rural area may make it more challenging to get the kind of care that you want. Often, there are not as many cancer specialists (oncologists) in rural areas as there are in a city or the suburbs. But there are other options you can explore. Perhaps there is another doctor in a nearby town where you could take part in a clinical trial.

Most states have at least one comprehensive cancer center where clinical trials are underway. (See our resource list

on page 16 for information on finding a center near you.) A comprehensive cancer center is a large hospital that specializes in caring for patients with all types of cancer, conducting clinical trials, and teaching the public about cancer. The National Cancer Institute selects these centers; there are more than 60 in 33 states. These centers may be far from your home, but sometimes the sponsor of the trial or organizations such as CancerCare® may be able to help you with travel expenses.

Q I'm 72 years old. Can I still take part in clinical trials?

A We used to think that because of their age, older adults would not be able to tolerate strong treatments. We now know that a person's overall health, rather than his or her age, is more important when it comes to clinical trials. Sometimes a clinical trial might be studying only patients in a certain age range. But in general, age alone should not prevent you from entering a trial. Researchers are encouraging older adults to take part in clinical trials so that seniors can receive the treatment benefits. Doctors also want to be sure that the medicines are, in fact, safe and effective for older people with cancer. Clinical trials are the best way to find out.

Q I've been told I can't be in some clinical trials because I have high blood pressure. Can trials exclude people with certain medical conditions?

A Yes, sometimes patients with certain conditions are excluded. The safety of patients in clinical trials comes first. If the researchers believe that high blood pressure or some other medical condition puts a person at risk, they will not enroll the person. However, you should talk to your doctor about your particular case. Each trial is different, and sometimes these decisions are made on a case-by-case basis. So you still might qualify for some clinical trials.

Q I'm in treatment and doing well. Should I enter a clinical trial?

A When treatment is going well, a person with cancer may still wonder if he or she should join a clinical trial. Talk with your doctor about whether the treatment you would receive in a clinical trial may improve upon the treatment you're already getting. Some trials study new treatments that may prevent the return of cancer after your initial treatment is complete. Your doctor may suggest you take part in one of these clinical trials in the future.

Resources

CancerCare

1-800-813-HOPE (4673)

www.cancer.org

American Cancer Society

1-800-227-2345

www.cancer.org

National Coalition for Cancer Survivorship

1-877-622-7937

www.canceradvocacy.org

Cancer.Net

Patient information from the American Society of Clinical Oncology

www.cancer.net

The Wellness Community

1-888-793-9355

www.thewellnesscommunity.org

To find out about clinical trials:

- Coalition of Cancer Cooperative Groups
1-877-520-4457
www.CancerTrialsHelp.org
- National Cancer Institute
1-800-422-6237
www.cancer.gov/clinicaltrials
- National Cancer Institute's Center for Cancer Research
1-888-624-1937
<http://bethesdatrials.cancer.gov>
- National Institutes of Health
www.clinicaltrials.gov

To find a comprehensive cancer center near you:

- National Cancer Institute
301-435-3848
<http://cancercenters.cancer.gov>



CANCER*care*[®]

The information presented in this patient booklet is provided for your general information only. It is not intended as medical advice and should not be relied upon as a substitute for consultations with qualified health professionals who are aware of your specific situation. We encourage you to take information and questions back to your individual health care provider as a way of creating a dialogue and partnership about your cancer and your treatment.

All people depicted in the photographs in this booklet are models and are used for illustrative purposes only.

This booklet was edited and produced by Elsevier Oncology.

© 2009 Cancer Care, Inc. All rights reserved.

11/09

When one word changes your world,

CANCERcare®

makes all the difference



With CancerCare,
the difference comes from:

- Professional oncology social workers
- Free counseling for you and your loved ones
- Education and practical help
- Up-to-date information

Our trusted team of professionally trained oncology social workers provides free counseling, education and practical help for you and your loved ones.



CANCERcare®

Help and Hope

1-800-813-HOPE (4673)

www.cancer.org