Entering a Clinical Trial

Is It Right for You?
About This Program

THIS AUDIOVISUAL PROGRAM AND BOOKLET WERE produced by Dana-Farber Cancer Institute in collaboration with Brigham and Women's Hospital, Massachusetts General Hospital, and the Beth Israel Deaconess Medical Center. They are for use by the Dana-Farber/Harvard Cancer Center and other institutions that offer cancer clinical trials. Funding for the production of this program was provided by the National Institute of Health (NIH) Human Subjects Research Enhancements Program.

We thank the patients, family members, and hospital staff members who generously volunteered their time to participate in this program. They described unique experiences in their own words, and their insights provided the core of the program. As we were putting together the program, we talked with patients, family members, health care providers, and others who offered differing points of view. These conversations helped us see that there were sections that required clearer descriptions and new topics that needed to be covered. They also helped us balance our description of the pros and cons of cancer clinical trials.
Committees that offered critical suggestions include the:

- Office for the Protection of Research Subjects
  Dana-Farber/Harvard Cancer Center
- Research/Program Nurse Council
  Dana-Farber Cancer Institute
- Department of Patient Family Education
  Dana-Farber Cancer Institute
- Patient and Family Advisory Council
  Dana-Farber Cancer Institute
- Patient-to-Patient, Heart-to-Heart
  Beth Israel Deaconess Medical Center
- Community Engagement Committee
  Dana-Farber/Harvard Cancer Center
- Multicultural Cancer Task Force
  Beth Israel Deaconess Medical Center
- The Wellness Community – Greater Boston

This program and booklet are dedicated to the patients who have taken part in cancer clinical trials. Without them, new treatments for cancer could not have been developed.
Our Goal

THIS PROGRAM WAS CREATED TO EXPLAIN THE DIFFERENT types of cancer clinical trials and their purpose. Our goal is to provide information that might help you decide whether or not to take part in a trial. The booklet reviews key information from the program and contains additional questions that you may want to ask.

We hope that this information is useful as you consider whether or not a clinical trial is right for you.
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What Is a Clinical Trial?

A CLINICAL TRIAL IS A RESEARCH STUDY that is done to answer important questions about medical care. If you choose to take part, you and the study team will work together to find out if a new method of cancer treatment, diagnosis, or prevention is effective.

In a clinical trial, researchers don’t know if the new method will be better than standard therapy for patients who are being treated now. What researchers do know is that clinical trials will result in better treatments for patients in the future.

Although there are many types of clinical trials, this program and booklet focus on trials that test new cancer drugs.

Taking part in a clinical trial is voluntary. Anyone can decide not to participate. If you decide to take part in a trial and then change your mind, you can also drop out of the trial at any time. Whatever decision you make, your doctors and nurses will make sure you get the best care possible for your disease.
What Are the Phases of Clinical Trials?

Phase I: How much of the new treatment can be given with reasonable safety?

The goal of a Phase I study is to find out three things:

- how much of a new drug can be given safely
- how often the drug needs to be given
- what the side effects of the new drug are

Generally, if you are one of the first patients to take part in a Phase I study, you will be given a small amount of the drug. This amount is based on animal testing or the safe dose of a similar medication given to other people. In some cases, it is based on the safe dose of the new drug given to people who took part in earlier studies of the drug. If there are no serious side effects, people who enroll later in the same study will receive more of the drug, until the study team learns the maximum amount of the drug that can be given and still be reasonably safe. About 20 to 30 people are included in Phase I studies. The studies are most often carried out at academic medical centers or large hospitals.
Important things to know about Phase I trials:

• Because you might be one of the first people in the world to receive the new drug, the side effects may not be known.
• Although this drug has shown promise in the laboratory or in animals, we don’t know if it will work against your cancer.

Phase II: Does the new treatment work for a specific type of cancer?

The goals of a Phase II study are to:

• continue to gather information about the safety of the drug
• test whether or not the drug works against a specific kind of cancer

In Phase II studies, patients with a specific type of cancer are given the highest dose of the new drug that is thought to be reasonably safe. This dose is based on results from Phase I studies. Generally, no more than 100 people are enrolled in Phase II studies. The studies are often carried out at major hospitals or academic medical centers, but they may also be conducted at local community hospitals.
An important thing to know about Phase II trials:

- When Phase II trials are conducted, researchers do not know whether or not the new drug will be effective against your cancer.

Phase III: Is the new treatment better than standard treatment for a specific type of cancer?

The goal of a Phase III study is to compare the new treatment to a standard (meaning current, state-of-the-art) treatment. Patients are assigned at random to a group that receives standard treatment or to a group that receives the new treatment. This means that the patient is assigned to a group by chance, like rolling dice or flipping a coin, and not by his or her doctor. The patient has an equal chance of being assigned to any one of the groups. Sometimes, the patient and the doctor don’t even know which group the patient is in.

Rarely, there is no effective standard treatment. If this is the case in a Phase III trial, then the new treatment may be compared to a current known treatment, supportive care, or a placebo (an inactive substance).
In Phase III studies, the treatment is given to hundreds or even thousands of people. The studies are carried out at many treatment centers nationwide.

**Important things to know about Phase III trials:**

- If the study team learns that one of the drugs is not effective or is too toxic, the study might be changed or stopped earlier than planned.
- At the beginning of the study, doctors don’t know if the new treatment is better than the standard treatment.
- Patients are assigned at random (by chance, like rolling dice or flipping a coin) to a group. Neither the doctor nor the patient is involved in the decision. In some cases, the patient and the doctor don’t know which group the patient is in.
How Are Patients Protected While on a Study?

THERE ARE THREE SYSTEMS in place to keep patients as safe as possible while taking part in a study: protocol review, eligibility, and monitoring.

Protocol Review

When a researcher wants to perform a clinical trial, he or she must prepare a detailed plan. This is called a protocol. The trial cannot be started until a group of people called the Institutional Review Board (IRB) has reviewed the protocol. The IRB must be satisfied that the trial addresses an important scientific question, is well planned, is as safe as possible, and is ethically sound. These groups are made up of physicians, nurses, scientists, pharmacists, and administrators who may work at the facility offering the trial, and at least one person who is not connected with the health care facility.

Federal institutions such as the U.S. Food and Drug Administration (FDA) or the National Cancer Institute (NCI) may also review the study. While the study is going on, the IRB receives regular updates to make
sure the study is being carried out as planned and that any safety issues are addressed promptly.

Eligibility, or Do You Fit the Group of People to Be Studied?

A patient must meet certain requirements to take part in a clinical trial. First, if your risk from being in the trial is greater than any possible benefit, you might not be able to join the study. Second, the people taking part in some trials must be similar to one another so the study team can learn if the new treatment works the same as or better than the standard treatment. Some examples of study criteria are age, disease type, the ability of body organs to work, and the ability of the person to carry out the normal activities of daily living.

Safety Monitoring, or How Will Side Effects Be Found Early?

Often, the study treatment has not been used in many people. In these cases it may be hard to predict what side effects might occur. During a study, the team will try to identify any potential side effects as quickly as possible. They may do more tests and physical exams than they would if someone were not taking part in a clinical trial. If you develop unexpected health problems, you would be treated promptly and may have to withdraw from the study.
What Might Help You Decide if Entering a Clinical Trial Is Right for You?

IF YOU ARE ELIGIBLE AND ARE THINKING about taking part in a study, it is important that you find out what options are available and that you think about them carefully. Don’t make a decision without getting as much information as you reasonably can.

Understand your choices.

Bring a trusted family member or friend with you when you meet with the study team to discuss options. That person can:

• ask questions
• write down the study team’s answers
• discuss the pros and cons of the study with you after the doctor’s visit

Find out what the study involves and what other options are available to you. Useful resources include:

• health care professionals, such as the study team, your primary care physician, or a second medical opinion
• personal contacts, such as family members and friends, other patients, or a support group
• the hospital’s patient and family resource center or library
• national organizations like the National Cancer Institute (NCI) or the American Cancer Society (ACS)
Meet with a financial counselor at the study site.

- He or she can contact your insurance company to find out if it will pay for the extra costs of taking part in the trial. Many insurance companies will pay for a lot of clinical trial-related services.

Use a professional medical interpreter if English is not your first language. That person will:

- make sure that the translation is accurate
- make it possible for family members or friends to act as advisors in the decision-making process
- know the medical terms so he or she can translate the medical information clearly and accurately

If you are feeling pressured by anyone, even a family member, to make a certain decision, you may always discuss your options with someone else. Possible sources of help include:

- spiritual leaders
- friends
- health care team members, such as your physician, nurse, or social worker
- psychologists and support group members

Remember that you don’t have to take part in research. You should not take part in the trial unless you feel it is right for you.
Questions You Might Ask the Study Team or Hospital Staff

What should I know about the study?
- Why is the study being done?
- Have there been other studies that evaluated this drug? If so, what were the results?
- Is it possible that I will be treated with an inactive substance (placebo) if I participate in the study?

What financial issues I should consider?
- Will my insurance company pay for any extra costs of participating in the trial?
- If I don’t have insurance, can I still be in the study?
- If I need long-term treatment for a health problem that might have been caused by the new treatment, will my insurance company pay for it?

How will my health care study team follow my care?
- Who are the health care professionals who will take care of me during the study?
- Will my primary care physician or primary oncologist be involved?
- If I withdraw from the study or if I change studies, will my health care team change?
- When the study is over, will the same doctors and nurses take care of me?
How will the study affect my overall health care?

- How are the study treatments and procedures different than the regular medical care that I might get if I decide not to take part?
- Will the study require that I be hospitalized? If so, for how long?
- Can I take my regular medications while I am in the study?
- If I enroll in the study, will I be able to find out my test results?
- If someone else in the study has an unexpected and severe health problem, will I be told?
- If I think the new treatment worked for me, will I be able to get the same treatment after the study ends?
- Will I need to keep getting tests done after I stop taking the study drug?
- Where will I be treated if I participate in the study?

What happens if I withdraw from the study?

- If I withdraw, will I continue to be cared for by the same health care team?
- Can I switch from one trial to another?

How do I get a medical interpreter, and how will his or her services be paid for?
Questions You Might Ask Yourself

BECAUSE EACH PERSON IS UNIQUE, what feels right to someone else might not feel right to you. In other words, when it comes to a clinical trial, you should make a decision based on your personal feelings and needs. Below is a list of questions you might want to ask yourself as you think about whether or not to take part in a clinical trial.

• Am I able to make the extra trips to the doctor or hospital that might be needed for the study?
• Do I have family or friends who can help me if I experience special problems during the trial, such as nausea, diarrhea, headaches, fever, or tiredness?
• Do I feel comfortable receiving a treatment whose risks and benefits are somewhat unknown?
• Would any of the possible side effects from receiving the study drug be unsatisfactory to me?
• Will I be able to manage if taking part in the trial means I might miss more work?
• If taking part in the study might cost me more money than standard treatment, would I be able to afford it?
• If I am very sick and have exhausted all other treatment options, would I rather receive treatment aimed at making me live comfortably and help me stay at home instead of being in a clinical trial that might cause side effects?
• Am I satisfied that my decision is right for me, and not a decision that is being made to please someone else?

This program and booklet were created to help you understand what clinical trials are and to help you decide whether or not to take part in a study. We hope you will write down any other questions or concerns and take this booklet with you when you discuss treatment options with the study team.

This program is not intended to be a substitute for discussions between you and your doctors or other members of your treatment or research team. If you are considering enrollment in a clinical trial, you are advised to get your questions answered by your physician and clinical trial study team before making your decision.
To Learn More

For General Information About Clinical Trials

National Cancer Institute (NCI)
1-800-4-CANCER (422-6237)
TTY: 1-800-332-8615
www.cancer.gov/clinicaltrials

American Cancer Society
1-800-ACS-2345 (227-2345)
www.cancer.org

Provides general information about clinical trials and also a national listing of clinical trials.

National Coalition for Cancer Survivorship
1010 Wayne Avenue, Fifth Floor
Silver Spring, MD 20910
1-877-NCCS-YES (622-7937)
www.canceradvocacy.org
For Information About Specific Clinical Trials

Dana-Farber/Harvard Cancer Center

www.dana-farber.org/clinicaltrials
Provides a listing of all clinical trials that are currently being done through Dana-Farber/Harvard Cancer Center, at Dana-Farber Cancer Institute, Brigham and Women’s Hospital, Massachusetts General Hospital, and Beth Israel Deaconess Medical Center.

U.S. National Library of Medicine’s List of Clinical Trials
www.clinicaltrials.gov
Provides current information about clinical research studies.

National Cancer Institute’s Clinical Studies Support Center (CSSC)
1-888-NCI-1937 (624-1937)
Provides general information about clinical trials as well as a listing of clinical trials currently taking place on the campus of the National Institutes of Health in Bethesda, Maryland.
To View This Program Using the Internet

Visit us at:
www.dana-farber.org/clinicaltrials

To Request a Copy of This Program

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Rose Films Inc.
“This is an honest and open account of clinical trials: why they are done, what people can learn, why patients should think about joining in - the pluses and minuses - the processes. The programme will really be able to help people make the right decision for them.”

Professor Sally Davies
Director of Research and Development
Department of Health, London

“Oh, it was great. You think you know everything about the mechanics of these trials and the video showed me a whole different layer.”

Mary Alice MacKay
Clinical trial participant
Dana-Farber Cancer Institute

“This inspiring, upbeat video can truly help educate patients about clinical trials. The real-life patients in this work are proof that informed people [help] to advance medical research and achieve the best possible clinical outcomes and patient satisfaction.”

George D. Demetri, MD
Director, Center for Sarcoma and Bone Oncology
Dana-Farber Cancer Institute and Harvard Medical School