A Patient's Guide to Clinical Trials

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What will we learn?

WHY PARTICIPATION IN CLINICAL TRIALS IS IMPORTANT

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Part 1
Clinical Trial Basics

- **What** are clinical trials?
- **Why** is participation in clinical trials important?
- What are the different **types** of clinical trials?
- What are the different **phases** of clinical trials?

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Part 2
How do clinical trials work?

- Protocols and basic guidelines
- Who can join a clinical trial?
- Randomization and placebo
- <u>Protection and Safety</u>
  - Informed Consent
  - 3 Review Boards
    - Scientific Review Panel
    - Institutional Review Board (IRB)
    - Data Safety Monitoring Committee (DSMC)

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Part 3
Deciding to Take Part

- What to consider
- Risks and benefits
- Costs
- Questions to ask
- How to find a trial

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Part One

CLINICAL TRIAL BASICS

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Clinical Trials are research studies that involve people.

Some of the reasons we do clinical trials are:

1. To learn if a new drug works and is safe
2. To learn if a new kind of treatment works better than the current treatment
3. To learn different ways to use a treatment that is already approved

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Clinical trials are the final step in a long process that begins with research in a lab and animal testing.

Most treatments used today are the result of past clinical trials.

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Why is participation in cancer clinical trials important?

Clinical trials contribute to the overall knowledge and progress against cancer.

In cancer, clinical trials are designed to answer questions about new ways to:

- Prevent cancer
- Find and diagnose cancer
- Treat cancer
- Manage symptoms of cancer or side effects from its treatment

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Types of Clinical Trials

AN OVERVIEW

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Types of Clinical Trials

- Prevention
- Screening
- Treatment
- Quality of Life/Supportive Care/Palliative Care

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Prevention Trials

- Cancer prevention trials are studies involving healthy people.
- Usually, the people who take part in prevention trials either do not have cancer, but are at high risk for getting cancer, or have had cancer and are at high risk for developing a new cancer.
- Prevention studies look at cancer risk, and ways to reduce that risk.

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Two types of prevention trials:

1. **Action studies** ("doing something")
   Focus on finding out whether actions people take—such as exercising more or eating more fruits and vegetables—can prevent cancer
2. **Agent studies** ("taking something")
   Focus on finding out whether taking certain medicines, vitamins, minerals, or dietary supplements (or a combination of them) may lower the risk of a certain type of cancer. Agent studies are also called chemoprevention studies

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Researchers who conduct prevention trials want to know:

- How safe it is for a person to take this drug or do this activity?
- Does the new approach prevent cancer?

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Screening Trials

- The goal of cancer screening trials is to test new ways to find disease early, when it may be more easily treated.
- An effective screening test will reduce the number of deaths from the cancer being screened.

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Researchers who conduct cancer screening studies want to know:

- Does finding disease earlier, before people have any symptoms, save lives?
- Is one screening test better than another?
- Do a large number of people who receive the screening test have unnecessary follow-up tests and procedures?

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Treatment Trials

Most cancer clinical trials are treatment studies that involve people who have cancer. These trials test new treatments or new ways of using existing treatments, such as new:

- Drugs
- Vaccines
- Approaches to surgery or radiation therapy
- Combinations of treatments, including some that work to boost your immune system to help fight the cancer

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Treatment trials are designed to answers questions like:

- What is a safe dose of the new treatment?
- How should the new treatment be given?
- Does the new treatment help people with cancer live longer?
- Can the new treatment shrink tumors or prevent them from growing and spreading to new places in the body?
- What are the new treatment's side effects?
- Does the new treatment allow a better quality of life with fewer side effects?
- Does the new treatment help prevent the cancer from coming back once treatment is finished?

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Quality of Life/Supportive Care/Palliative Care Trials

- These trials look at ways to improve the quality of life of cancer patients, especially those who have side effects from cancer and its treatment.

- They find new ways to help people cope with pain, nutrition problems, infection, nausea and vomiting, sleep disorders, depression, and other health problems.

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Quality of Life/Supportive Care/Palliative Care Trials, cont.

- These studies might test drugs, such as those that help with depression or nausea.
- They might test activities, such as attending support groups, exercising, or talking with a counselor.
- Some trials test ways to help families and caregivers cope with their own needs, as well as those of the person with cancer.

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Researchers who conduct these studies want to know:

- How does cancer and its treatment affect patients and their loved ones?

- What can improve the comfort and quality of life of people who have cancer?

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Clinical Trial Phases

PHASES 1-4

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Phases of Clinical Trials

- For a treatment to become standard, it must first go through 3 or 4 clinical trial phases.
- The early phases make sure the treatment is **safe**.
- Later phases show if it **works better** than the standard treatment.

You do not have to take part in all phases.

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Phase I

Purpose:

- To find a safe dose
- To decide how the new treatment should be given
- To see how the new treatment affects the human body

Number of people taking part:

- 15–30

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Phase 2

Purpose:

- To determine if the new treatment has an effect on a certain cancer
- To see how the new treatment affects the human body

Number of people taking part:

- Less than 100

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Phase 3

Purpose:

- To compare the new treatment (or new use of a treatment) with the current standard treatment

Number of people taking part:

- From 100 to several thousand

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Phase 4

Purpose:

- To further assess the long-term safety and effectiveness of a new treatment

Number of people taking part:

- Several hundred to several thousand

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Part 2

HOW DO CLINICAL TRIALS WORK?

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Clinical trials follow strict guidelines

- The guidelines clearly state who will be able to join the study and the treatment plan.

- Every trial has a person in charge, usually a doctor, who is called the **principal investigator**.

- The principal investigator prepares a plan for the study, called a **protocol**, which is like a recipe for conducting a clinical trial.

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About Protocols

The protocol explains what the trial will do, how the study will be carried out, and why each part of the study is necessary.

It includes information about:

- The reason for doing the study
- Who can join the study
- How many people are needed for the study
- Any drugs they will take, the dose, and how often
- What medical tests they will have and how often
- What information will be gathered about them

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Who can join a clinical trial?

Based on the questions the research is trying to answer, each clinical trial protocol clearly states who can or cannot join the trial. Common criteria for entering a trial include:

- Having a certain type or stage of cancer
- Having received a certain kind of therapy in the past
- Being in a certain age group

Criteria such as these help ensure that people in the trial are as alike as possible. This way doctors can be sure that the results are due to the treatment being studied and not other factors.

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These criteria also help ensure:

Safety

- Some people have health problems besides cancer that could be made worse by the treatments in a study. If you are interested in joining a trial, you will receive medical tests to be sure that you are not put at increased risk.

Accurate and meaningful study results

- You may not be able to join a clinical trial if you already have had another kind of treatment for your cancer; it may make it difficult to determine your results were due to the treatment being studied or the earlier treatment.

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Randomization

PREVENTING BIAS

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What is Randomization?

- Randomization is a process used in some clinical trials to prevent bias.
- Bias occurs when a trial's results are affected by human choices or other factors not related to the treatments being tested.
- Randomization helps ensure that unknown factors do not affect trial results.

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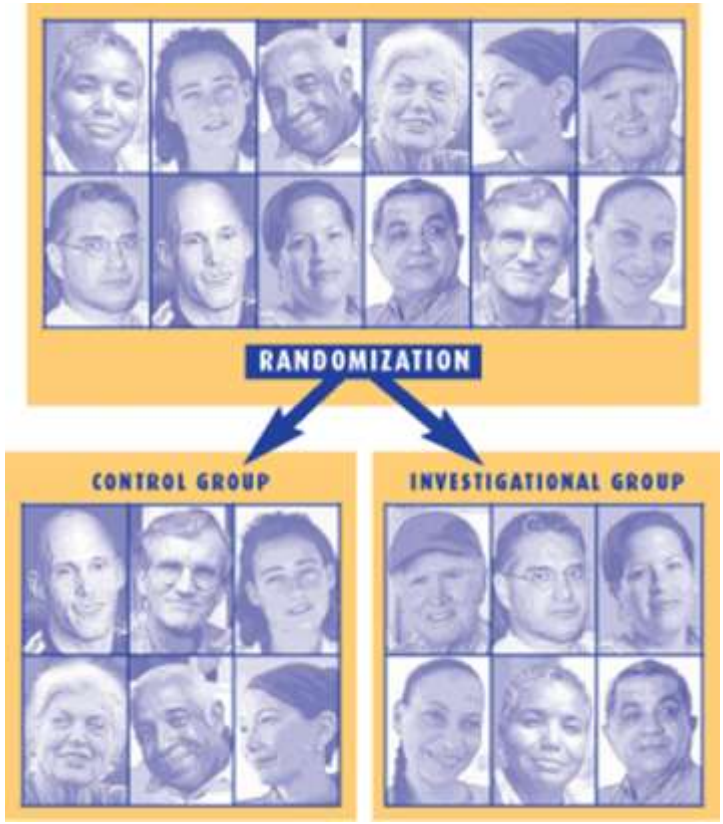
How does Randomization work?

In a randomized trial, you are assigned by chance to either a “control group” or an “investigational” group.



- If you are assigned to the **control** group, you will get the most widely accepted treatment **(standard treatment)** for your cancer.
- If you are assigned to the **investigational** group, you will get the **new treatment** being tested.

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More on Randomization

- Assignment to groups is done by chance (like the flip of a coin). Usually the assignment is done with a computer program or a table of random numbers.
- Comparing these control and investigational groups to each other often clearly shows which treatment is more effective or has fewer side effects.
- **If you are thinking about joining a randomized clinical trial, you need to understand that there is an equal chance you will be assigned to either group. Neither you nor your doctor chooses which group you will be in.**

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Placebo

- A placebo is a substance made to look like the medicine being tested, but it is not an active drug (sometimes called a “sugar pill.”) Placebos are sometimes used in clinical trials, but **are rarely used in *cancer* clinical trials.**
- In some cases, a study may compare standard treatment plus a new treatment, to standard treatment plus a placebo. You will be told if the study uses a placebo.

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For Your Protection

ARE CLINICAL TRIALS SAFE?

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For Your Protection

Federal rules help ensure that clinical trials are ethical.

Your rights and safety are protected through:

- The informed consent process
- Careful review and approval of the clinical trial by multiple review committees
- Your research team

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Informed Consent

IT'S A PROCESS

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What is Informed Consent?

- Informed consent is a **process** through which you learn the purpose, risks, and benefits of a clinical trial before deciding whether to join.
- It is a critical part of ensuring patient safety in research.
- During the informed consent process you learn important information about a clinical trial. This information can help you decide whether to join.

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How does Informed Consent work?

The research team, which is made up of doctors and nurses, first explains the trial to you. The team explains the trial's:

- Purpose
- Tests and procedures
- Treatment
- Risks and benefits

They will also discuss your rights, including your right to:

- Make a decision about participating
- Leave the study at any time

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Before agreeing to take part in a trial, you have the right to:

- Learn about all your treatment options
- Learn all that is involved in the trial—including all details about treatment, tests, and possible risks and benefits
- Discuss the trial with the principal investigator and other members of the research team
- Both hear and read the information in language you can understand

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More on Informed Consent

- After discussing all aspects of the study with you, the study team will give you an informed consent form to read.
- The form includes written details about the information that was discussed and also describes the privacy of your records.
- If you agree to take part in the study, you sign the form. But even after you sign the consent form, you can leave the study at any time.
- If you decide to leave the study, your doctor will discuss other treatment options with you.

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Committee Review

Federal rules require that cancer clinical trials go through careful review and approval by at least three different types of committees before patients can enroll:

Scientific Review Panel

- A group of experts reviews a clinical trial protocol to make sure it is based on sound science. All clinical trials that are funded by the Government must go through this review.

Institutional Review Board (IRB)

- IRBs assure that the rights and welfare of humans participating in research are protected. They make sure the research follows all federal, institutional, and ethical guidelines. IRBs also closely watch the ongoing progress of the trial from beginning to end.

Data Safety Monitoring Committee

DSMCs monitor trials for patient safety and effectiveness while the study is ongoing. They:

- Ensure that any possible risks are reduced as much as possible
- Ensure that the data are sound
- Stop a trial if safety concerns come up or as soon as its objectives have been met.

Part 3

DECIDING TO TAKE PART

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Making decisions

Whenever you need treatment for your cancer, clinical trials may be an option for you.

Choosing to join a clinical trial is something only you, those close to you, and your doctors and nurses can decide together.

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Weighing the Pros and Cons

Possible Benefits

- Clinical trials offer high-quality cancer care. If you are in a randomized study and do not receive the new treatment being tested, you will receive the best known standard treatment. This may be as good as, or better than, the new approach.
- If a new treatment is proven to work and you are receiving it, you may be among the first to benefit.
- By looking at all your treatment choices, including clinical trials, you are taking an active role in a decision that affects your life.
- You have the chance to help others and improve cancer treatment.

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Possible Drawbacks

- New treatments under study are not always better than, or even as good as, standard care.
- If you receive standard care instead of the new treatment being tested, it may not be as effective as the new approach.
- New treatments may have side effects that doctors do not expect or that are worse than those of standard treatment.
- Even if a new treatment has benefits, it may not work for you. Even standard treatments, proven effective for many people, do not help everyone.
- Health insurance and managed care providers may not cover all patient care costs in a study. What they cover varies by plan and by study.

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Costs - 2 Types

1. Patient Care Costs

Theses are costs related to treating your cancer, whether you are in a trial or receiving standard therapy. These costs are often covered by health insurance. They include:

- Doctor visits
- Hospital stays
- Standard cancer treatments
- Treatments to reduce or eliminate symptoms of cancer or side effects from treatment
- Lab tests
- X-rays and other imaging tests

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More on patient care costs

- You or your insurance company are usually expected to pay the routine patient care costs that are performed during a clinical trial. This is because you would receive routine procedures as part of your regular medical care.
- You would be responsible for co-pays, deductibles and co-insurance, as applicable to your insurance policy. You may want to check with your insurance company to see what your costs will be.
- If you have a Medicare Advantage Plan, routine care related to the study is required to be billed to Medicare first, rather than your Advantage Plan. Your Medicare Advantage Plan will be billed as a secondary payer. You will be responsible for any co-pays related to these routine services. You may want to check with your Advantage Plan Representative to clarify what your costs will be.

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Costs

2. Research Costs

These are costs related to taking part in the trial. Often these costs are not covered by health insurance, but they may be covered by the trial's sponsor.

Examples include:

- The study drug
- Lab tests performed purely for research purposes
- Additional x-rays and imaging tests performed solely for the trial

You may have extra doctor visits that you would not have with standard treatment. During these visits your doctor carefully watches for side effects and your safety in the study. These extra visits can add costs for transportation and child care.

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Questions to Ask

TO HELP YOU DECIDE

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Questions About the Trial

- Why is this trial being done?
- Why do the doctors who designed the trial believe that the treatment being studied may be better than the standard treatment? Why may it not be better?
- How long will I be in the trial?
- What kinds of tests and treatments are involved?
- What are the possible side effects or risks of the new treatment?
- What are the possible benefits?
- How will we know if the treatment is working?

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Questions About Risks and Benefits

- What are the possible side effects or risks of the new treatment?
- What are the possible benefits?
- How do the possible risks and benefits of this trial compare to those of the standard treatment?

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Questions About Your Rights

- How will my health information be kept private?
- What happens if I decide to leave the trial?

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Questions about Costs

- Will I have to pay for any of the treatments or tests?
- What costs will my health insurance cover?
- Who pays if I am injured in the trial?
- Are there extra visits that will add costs for transportation and/or child care?

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Questions About Daily Life

- How could the trial affect my daily life?
- How often will I have to come to the hospital or clinic?
- Will I have to stay in the hospital during the clinical trial? If so, how often and for how long?
- Will I have to travel long distances to take part?
- Will I have check-ups after the trial?

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Comparing Choices

- What are my other treatment choices, including standard treatments?
- How does the treatment I would receive in this trial compare with the other treatment choices?
- What will happen to my cancer without treatment?

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In Closing

REMEMBER YOUR RIGHTS

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Clinical Trials are VOLUNTARY

- You can choose not to take part or withdraw from taking part at any time.
- Your future treatment and/or relationship with your doctor will not be affected by your decision.
- You are encouraged to ask questions or voice concerns.

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Where Can I Find a Clinical Trial?

- The National Cancer Institute, drug companies, medical institutions, and other organizations sponsor clinical trials.
- Clinical trials take place in many settings, such as cancer centers, large medical centers, small hospitals, and doctors' offices.
- The National Cancer Institute keeps a list of thousands of cancer clinical trials. Contact them to see which ones you might be eligible for.

To reach the National Cancer Institute:

Call: 1-800-4-CANCER (1-800-422-6237)
Visit: http://www.cancer.gov
Chat: http://www.cancer.gov/livehelp
E-mail: cancergovstaff@mail.nih.gov

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References

- National Cancer Institute - Taking Part in Cancer Treatment Research Studies, NIH Publication No. 12-6249, Revised September 2011
- National Cancer Institute – Clinical Trials Information for Patients and Caregivers, https://www.cancer.gov/about-cancer/treatment/clinical-trials

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Questions?

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