What is a Clinical Trial?

Introduction to Clinical Trials and Addressing Questions Related To Cost, Efficacy and Care

Clinical Trials: Why take part in one?

Clinical trials are research studies that involve people. Through clinical trials, doctors find new ways to improve treatments and the quality of life for people with disease.

Researchers design cancer clinical trials to test new ways to:

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

https://www.cancer.gov/about-cancer/treatment/clinical-trials

Clinical Trials: Why take part in one?

Clinical trials are the final step in a long process that begins with research in a lab. Before any new treatment is used with people in clinical trials, researchers work for many years to understand its effects on cancer cells in the lab and in animals. They also try to figure out the side effects it may cause.

https://www.cancer.gov/about-cancer/treatment/clinical-trials

Clinical Trials: Why take part in one?

Types of Clinical Trials

- There are several types of cancer clinical trials, including treatment trials, prevention trials, screening trials, and supportive and palliative care trials. Each type of trial is designed to answer different research questions and will help researchers learn things that will help people in the future.

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Clinical Trials: Why take part in one?

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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Clinical Trials: Why take part in one?

Treatment trials are designed to answers questions such as:

- 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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Clinical Trials: Why take part in one?

Many newer treatment trials require people to have their tumors tested for genetic changes first to see if treatments targeting specific changes might work better for them than standard treatments.

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Phases of Clinical Trials

Phase 1

Purpose:

- To find a safe dose
- To decide how the new treatment should be given (by mouth, in a vein, etc.)
- To see how the new treatment affects the human body and fights cancer
- Number of people taking part: 15–30

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Phases of Clinical Trials

Phase 2

Purpose:

- To determine if the new treatment has an effect on a certain cancer
- To see how the new treatment affects the body and fights cancer
- Number of people taking part: Less than 100

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Phases of Clinical Trials

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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How do I know if a Clinical Trial is right for me?

Like all treatment options, clinical trials have possible benefits and risks. By looking closely at all options, including clinical trials.

When deciding about taking part in a clinical trial it's important to discuss the risks and benefits with your provider.

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How do I know if a Clinical Trial is right for me?

Questions about the Trial

- What is the purpose of the trial?
- Why do the researchers believe that the treatment being studied may be better than the one being used now? Why may it not be better?
- How long will I be in the trial?
- What kinds of tests and treatments are involved?
- How will the doctor know if the treatment is working?
- How will I be told about the trial's results?
- How long do I have to make up my mind about joining this trial?
- Who can I speak with about questions I have during and after the trial?
- Who will be in charge of my care?
- Is there someone I can talk to who has been in the trial?

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How do I know if a Clinical Trial is right for me?

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?

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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How do I know if a Clinical Trial is right for me?

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'm injured in the trial?
- Who can help answer any questions from my insurance company?

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?
- Will I have check-ups after the trial?

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How do I know if a Clinical Trial is right for me?

Questions about 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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What's in it for me?

Possible Benefits

- You will have access to a new treatment that is not available to people outside the trial.
- The research team will watch you closely.
- If the treatment being studied is more effective than the standard treatment, you may be among the first to benefit.
- The trial may help scientists learn more about cancer and help people in the future.

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What's in it for me?

Possible Risks

- The new treatment may not be better than, or even as good as, the standard treatment.
- New treatments may have side effects that doctors do not expect or that are worse than those of the standard treatment.
- You may be required to make more visits to the doctor than if you were receiving standard treatment. You may have extra expenses related to these extra visits, such as travel and childcare costs.
- You may need extra tests. Some of the tests could be uncomfortable or time consuming.
- Even if a new treatment has benefits in some patients, it may not work for you.
- Health insurance may not cover all patient care costs in a trial.

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Am I eligible?

Every clinical trial has a protocol, or study plan, that describes what will be done during the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot take part in the trial. These guidelines are called eligibility criteria.

Common eligibility criteria include:

- Having a certain type or stage of cancer
- Having received (or not having received) a certain kind of therapy in the past
- Having specific genetic changes in your tumor
- Being in a certain age group
- Medical history
- Current health status

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Is this going to cost me?

As you think about taking part in a clinical trial, you will face the issue of how to cover the costs of care.

There are two types of costs associated with a clinical trial:

Patient care costs and Research costs.

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Is this going to cost me?

Patient care costs are those 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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Is this going to cost me?

Research costs are those 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
- When you take part in a 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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How do I know it's safe?

If you are thinking about taking part in a clinical trial, you may have questions such as:

- Are there risks to taking part in the trial?
- Who is watching out for any problems?
- Who is making sure that participants are safe?
- Is the trial trying to answer an important research question?

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How do I know it's safe?

In fact, there are federal rules in place to help ensure the safety and ethics of clinical trials. You will be protected through:

- The informed consent process
- Careful review and approval of the clinical trial protocol by:
  - Scientific experts
  - An institutional review board (IRB)

Ongoing monitoring of the trial by:

- The IRB
- Data and Safety Monitoring Boards (DSMBs) for phase 3 trials
- The organization sponsoring the trial
- The research team

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Resources

- www.clinicaltrials.gov National Institutes of Health
- www.cancer.gov National Cancer Institute
- www.cancer.org American Cancer Society
- www.pancan.org Pancreatic Cancer Action Network

https://www.cancer.gov/about-cancer/treatment/clinical-trials

QUESTIONS?