Ready with Knowledge: A Cancer Clinical Trials Primer

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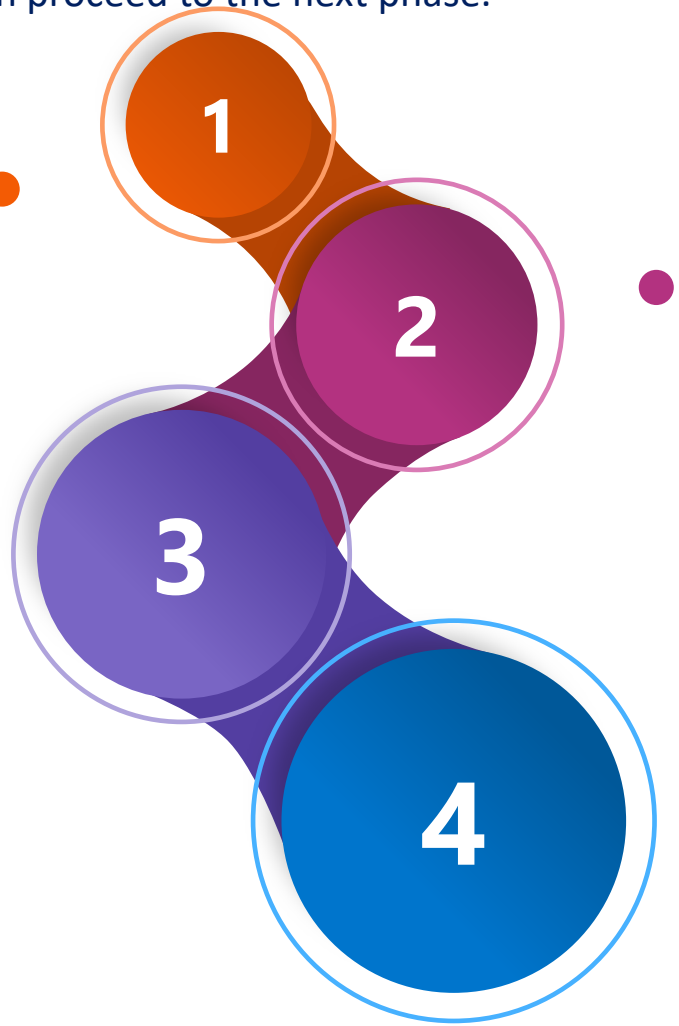
The Four Phases of Clinical Trials

Clinical trials ensure that treatments are safe and effective and are conducted in steps called phases. Each phase answers different questions about how a treatment works. Safety is a priority in every phase. Data from each phase must be reviewed and approved by the U.S. Food and Drug Administration (FDA) before the treatment can proceed to the next phase.



Phase 1

Researchers test safety and side effects of a treatment for the first time in a small group of people (20 to 80 people)

Phase 2

The effectiveness and safety of the treatment is studied in a larger group of people (100 to 300 people)

Phase 3

Researchers test effectiveness, monitor side effects, and evaluate safety of the treatment in comparison with other treatments in a large group of people (1000 to 3000 people)

Phase 4

Researchers track safety, effectiveness, and optimal use of the treatment AFTER it is FDA-approved and available to the public (general population)

References: https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

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Learning the LINGO

Clinical trials are medical research studies that test the safety and effectiveness of new treatments in people (instead of animal subjects). Here are a few common terms used in clinical trials.

Site

The medical center where a clinical trial takes place

Sponsor

The entity (person/institution/company/government agency) responsible for initiating and overseeing a clinical trial

Principal Investigator

The doctor leading the clinical research team and overseeing the monitoring of study participants' health

Investigational drug

The medication or treatment that is being tested in a clinical trial

Placebo

A pill or liquid that has no medicinal value but looks like the treatment being tested

Blinded

Neither the researchers nor the patients know who is receiving which treatment (placebo or investigational drug) in a trial

References: https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms; https://pubmed.ncbi.nlm.nih.gov/20815294/

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Protocol

Documented plan of the design, objectives, procedures, type of patients who could participate, safety measures, and ethical issues pertaining to the clinical trial

Inclusion & Exclusion Criteria

Inclusion: Factors that make someone eligible to participate.
Exclusion: Factors that prevent someone from participating.

Informed Consent

Explanation of risks and benefits of the clinical trial that helps someone decided if they want to participate or not

Participant

A patient with a specific health condition who volunteers to take part in the clinical trial and who meets the eligibility criteria

Randomization

The process by which participants are assigned by chance to a treatment group (either receiving placebo or the investigational drug)

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Biomarkers

Genes, proteins, or other substances found in cancer cells (and sometimes normal cells) that give information on how the tumor will grow and respond to treatment

Subtype

Classification of cancer based on unique characteristics, such as biomarkers, beyond the location of origin, e.g., ER+ breast cancer or squamous NSCLC

Genetics

Study of your genes, fragments of deoxyribonucleic acid (DNA), that determine all inherited traits including susceptibility to certain cancers

Screening

Testing for cancer in someone who is not showing any symptoms, e.g., annual mammograms for breast cancer or chest x-rays for lung cancer

Endpoints

The major outcomes that are measured in a clinical trial, e.g., the percentage of patients whose tumors shrank due to the investigational drug compared to those on placebo

Mutation

A change in the DNA of a cell that may lead to the development of cancer

References: https://www.understandcancertogether.com/understand-cancer/types-of-cancer/; https://www.cancer.org/treatment/understanding-your-diagnosis.html; https://www.cancer.org/cancer/glossary.html

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Journey through the Process

Whether you are considering a clinical trial for yourself or a loved one, this may be a new process for you. Here is a preview of what this journey will be like.

Informed Consent

Before you decide to participate, contact the research team running the trial. They will provide you with trial information, including possible risks and benefits, safety precautions, your rights, and more. This will help you decide if participating is a good option for you. If it is, you would then give your consent which is your agreement to participate in the trial. **Ask as many questions as possible during this process so you can make an informed decision.**

Medical Screening

Imaging or laboratory tests (for example, blood or urine tests) will be needed to confirm that you are eligible for the trial and will be safe throughout your participation. Having this information will help researchers monitor how your body responds to the new treatment. **Researchers will also ask you to share your medical history, including your cancer diagnosis, pathology reports, tumor testing, and any past treatments.**

Lifestyle Preparation

Clinical trials impact you and your family. Some studies take place in your area, while others may require you to travel, taking you and your caregiver away from your home/jobs/support system for periods of time. The investigational drug is provided at no cost, but some parts of your routine patient care will be billed to your health insurance. **The trial sponsor might not cover non-treatment costs, such as travel and lodging, so be sure to ask about this.**

During the Clinical Trial

You will be closely monitored by the research team during the trial. This means having appointments and tests more often so researchers can monitor how the treatment is affecting you. **If you decide that you no longer want to participate, you can leave the trial at any time.**

Following Up

Participants must attend their follow-up appointments and provide information needed by researchers to monitor their progress. This is important, even after the trial has ended, so that the FDA could have complete and sufficient information to decide if a treatment should be approved and made available to the public.

References: https://www.verywellhealth.com/breast-cancer-clinical-trials-6746171; https://patienteducation.asgct.org/patient-journey/considering-a-clinical-trial

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