

Clinical Trials – The Basics

By Joni Venticinque July 2023

Cancer clinical trials are research studies involving human participants investigating new cancer treatments. They play a crucial role in advancing medical knowledge and improving patient outcomes. These trials evaluate the safety and effectiveness of new interventions, such as drugs and surgical techniques, imaging techniques, and medical devices. The primary goal is to generate scientific evidence regarding these interventions' safety, effectiveness, and potential side effects. Let us look at the different phases of cancer clinical trials and some trusted resources for information and clinical trial searches.

The Four Phases of Cancer Clinical Trials

Cancer clinical trials typically follow a sequential progression through four distinct phases, each serving a specific purpose in evaluating new treatments.



Safety



Phase 1: Safety and Dosage Determination

Phase 1 trials are the first step in testing a new treatment. They focus on determining the treatment's safety, dosage, and side effects. A small number of healthy volunteers or patients (20-80) with advanced cancer participate in these trials. The goal is to find the highest dose that can be given safely.



Safety
& Dosing



Phase 2: Efficacy Evaluation

Phase 2 trials involve a larger group of patients (100-300) and evaluate the effectiveness of the treatment. Researchers monitor patients' responses and assess short-term side effects. These trials provide preliminary evidence of whether the treatment works.



Safety
& Efficacy



Phase 3: Comparative Analysis

Phase 3 trials compare the new treatment to the current standard of care or alternative therapy. They involve a large number of patients (300-3,000) from diverse populations who are randomly assigned to receive either the new treatment or the standard treatment. The goal is to determine if the new treatment is better or equivalent to existing treatments in terms of effectiveness and safety. Typically Phase 3 trials are needed to get a drug approved for use as standard of care.



Post Marketing
Surveillance



Phase 4: Post-Approval Monitoring

Phase 4 trials take place after regulatory approval and focus on long-term safety and additional benefits of the approved treatment. They collect real-world data and evaluate the treatment's effectiveness in diverse patient populations.

Inclusion/Exclusion Criteria

Inclusion criteria are the conditions a person with cancer must meet to participate in the trial. In contrast, **exclusion criteria** are the conditions that a person with cancer cannot have to join the trial. These criteria play a crucial role in ensuring that the participants in the trial are similar in terms of their cancer type and overall health, which helps to eliminate the influence of chance on the trial results. With the advancements in genomic testing of tumors, inclusion criteria are becoming narrower as trials are being conducted for more specific gene mutations. It is important for patients to consult their healthcare team to determine if they qualify for a particular trial.

Reliable Resources for Clinical Trial Education

Cancer.Net®

Cancer.net a trusted resource by the American Society of Clinical Oncology (ASCO), provides comprehensive information about clinical trials. Lists covering various aspects of clinical trials, such as general questions, logistics, risks and benefits, and costs, address common concerns and provide clarity to potential participants. The search function on Cancer.net allows users to search for trials based on cancer type, location, and eligibility criteria, making it easier to find relevant clinical trials.

<https://www.cancer.net/research-and-advocacy/clinical-trials/questions-ask-about-clinical-trials>

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PRE-ACT

PRE-ACT (Preparatory Education About Clinical Trials) is an educational program that provides general information about clinical trials. PRE-ACT delivers clinical trial information through a series of short videos. You may view the entire library of these videos or choose to have PRE-ACT personalize your videos based on your feedback to learn more about clinical trials and make informed decisions.

<https://www.cancer.net/research-and-advocacy/clinical-trials/welcome-pre-act>



Clinical trials glossary from the NIH:

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms>

ClinicalTrials.gov

ClinicalTrials.gov is a publicly accessible database providing comprehensive clinical trial information. You can search for trials based on various criteria, including the condition, intervention, location, and sponsor. <https://clinicaltrials.gov>

antidote //

Antidote.me is a user-friendly platform that helps connect patients with clinical trials. You can be matched with relevant trials by providing your health information and preferences. <https://www.antidote.me>

CureIt

CureIt is a mobile application that helps patients and physicians find appropriate clinical trials by providing basic information about the disease. It can be downloaded from the Appstore or Google Playstore.

If you are looking for clinical trials for a specific disease, advocacy websites dedicated to that disease can be helpful. For example, the American Lung Association, Ovarian Cancer Research Alliance, BreastCancerTrials.org, and Prostate Zero Cancer Foundation have trial finders specific to their respective diseases. Links are below:

<https://www.lung.org/research/clinical-trials>

<https://ocrahope.org/patients/diagnosis-and-treatment/ovarian-cancer-clinical-trials>

<https://www.breastcancertrials.org>

<https://zerocancer.org/learn/current-patients/clinical-trials/find-a-clinical-trial/>

By participating in cancer clinical trials, patients not only gain access to innovative treatments but also contribute to scientific progress and the future of cancer care. If you need more information or assistance in finding a clinical trial, feel free to reach out to Joni Venticinque at, joni@thesecondopinion.org.

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