CANCER GUARDIAN™
Comprehensive Cancer Support

Clinical Trials Information Guide

Understanding the process and benefit for patients

WGA
Wamberg Genomic Advisors

Let’s start with the basics - what is a clinical trial?

Clinical trials are studies designed to find new and better ways to treat diseases. The medical community relies carefully designed clinical trials to determine whether a new treatment is safe and effective for patients.

These studies are necessary to create new and more effective treatments for diseases such as cancer. Anyone can participate in a clinical trial if they meet the criteria specified.

What specific criteria are involved for trials?

Cancer therapies are moving away from the one-size-fits-all model. We want to know about the specific molecular and genetic makeup of each tumor and deploy a therapy that targets that; this is the essence of what we call “precision medicine”.

In order to enroll in a clinical trial the patient often require specific “biomarkers,” or a substance made by cancer cells, in order to enroll. To find out whether the tumor has certain alterations, your doctor will order “comprehensive genomic profiling” of the tumor.

“Eligibility” is what allows a patient to participate in a clinical trial and is very specific. The factors that allow someone to participate in a clinical study are called “inclusion criteria.” So a particular biomarker might be one of these. The factors that disqualify someone from participating are called “exclusion criteria.” Both inclusion and exclusion criteria are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

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Why are clinical trials in oncology more important than ever?

The rapid demand for precision drugs creates a huge challenge to conduct appropriate and efficient clinical trials to keep up with the new pipeline of new proposed treatments in precision settings. It takes a trial SIX YEARS before it can ever reach a human.

After a drug has gone through a clinical trial, it then another takes another EIGHT YEARS before hitting the FDA approved market. This is one reason why it can be extremely beneficial to take part in a clinical trial-- these drugs are not available to the general public yet.

Here is another fact to consider: the proportion of trials requiring the presence or absence of a genomic alteration increased more than FIVE TIMES between 2006 and 2013 and the demand continues to grow. Remember, this is what we find out from doing comprehensive genomic profiling.

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Who conducts a clinical trial?

Every clinical study is led by a principal investigator, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.

Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, in addition to Federal agencies such as the National Institutes of Health, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. Doctors, other health care providers, and other individuals can also sponsor clinical research.

This means that a clinical trial can take place in various locations. Oncology trials are typically conducted at Comprehensive Cancer Centers (the highest NCI designation) because they are typically larger research institutions that have the resources and capacity to carry out the study protocol.

How do I find the right clinical trial for me?

There are approximately 70,000 cancer studies going on worldwide at any given time.

Some experts estimate that even a Comprehensive Cancer Center will only know about 10% of trials going on in the United States. In other words, there is no single overarching body that controls clinical trials or can match you to the appropriate one.

Of course there are various sites that offer some insight to patients and their families, but unfortunately, they are often out of date.

This is why Cancer Guardian includes the Clinical Trial Navigator platform. Our Cancer Support Specialists work with diagnosed members to find the most suitable clinical trial options and help with enrollment.

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Why aren’t there more people on clinical trials?

There are several reasons. First, scientific advances are moving far quicker than the FDA can approve new medications. Comprehensive genomic profiling, which allows us to understand which biomarkers the therapy should target, has yet to be approved for all disease processes by the FDA.

For this reason, Medicare and insurance companies may refuse to reimburse for these tests, which can cost the patient up to $10,000 out of pocket. Gradually, we will begin to see an uptake in the routine profiling of certain tumors, but more clinical trials need to be done before the FDA can approve treatments that require tumor profiling as the new “standard of care.”

Second, unless the hospital is directly involved in the clinical trial, many physicians are unaware of the current clinical trials being conducted.

Are clinical trials a “last resort”?

Historically, the medical community considered clinical trials as a “last resort” or something to do if the current therapy turned out to be ineffective or stopped working. The standard of care used to be chemotherapy, which does not discriminate between healthy cells and cancer cells. In other words, chemotherapy was given to all patients, caused horrible side effects, and we could not determine why it worked for some people and not for others.

In the age of precision medicine, however, our ability to predict which patient will respond to which drug is getting better and better. In fact, one school of thought says that clinical trials can and should be used as a “first-line” treatment if there is a targeted therapy available at the right time.

Remember, targeted therapies attack the cancer cells only, cause fewer side effects and have far better health outcomes.