







CLINICAL TRIALS Info Sheet.



As many as 50% of Roswell Park patients are eligible to join a clinical trial.

WHAT YOU SHOULD KNOW

All the cancer drugs and therapies used today came about after many years of research. Clinical trials are the final stages of this research where physicians and scientists work together to evaluate a promising new treatment or approach. A clinical trial may study or test a new:

- approach to diagnose or prevent cancer
- drug or method to treat cancer
- way to use or combine existing treatments

When clinical trials identify better, more effective and/or less toxic approaches, these new therapies can eventually become the standard of care.

WHY SHOULD YOU CONSIDER A CLINICAL TRIAL?

Enrolling in a trial may be the only way to get a particular kind of treatment.

If a new treatment is proven effective, you may be among the first to benefit.

lt's an opportunity to help others and improve cancer treatment.



Each patient enrolled in a study is assigned a clinical research coordinator who ensures you receive the appropriate care.

ARE CLINICAL TRIAL TREATMENTS A BETTER FIRST OPTION?

For some patients, yes. We can now identify certain mutations, characteristics or abnormalities of some cancer cells and researchers are now developing treatments that target or attack these specific abnormalities, thereby killing cancer cells more effectively.

A study drug that targets a genetic characteristic of your tumor could offer your best option. Some of these treatments have already become standard of care. One example is Herceptin, which targets breast and stomach cancers that show abnormal activity of a protein called HER-2. Many more treatments are currently available only through clinical trials.



SETTING THE RECORD STRAIGHT

Many people misunderstand the purpose of clinical trials and how they're conducted. Learn the facts you need to make an informed decision about whether to participate.



I could get a placebo (pill, liquid or powder) that contains no medicine instead of treatment.



Few cancer clinical trials use placebos, and they are never given in place of a treatment. A study may compare standard treatment plus a new treatment to standard treatment plus a placebo. You will be told if a study uses a placebo.

People only enroll in a clinical trial after trying all other options.



Many patients enroll in a study because it's their best option, before any treatment. Some studies don't involve treatment, but examine new ways to prevent cancer or its recurrence.

Because Roswell Park is a research institution, patients are required to participate in studies.



About half our patients are eligible for a trial, but it's only an option. IT IS ENTIRELY THE PATIENT'S DECISION.

Once you enroll in a trial, you cannot change your mind.



You may choose to leave a trial at any time, for any reason.

ROSWELL PARK'S CLINICAL RESEARCH CENTER

As one of the first in the nation to focus specifically on developing new cancer treatments, our center provides more treatment options through clinical trials, offers the highest level of patient safety and quickly generates precise data on potential new treatments.

Roswell Park has a strong history of cancer research success. Among other milestones, we:

- · launched the first chemotherapy research program in the United States in 1904
- developed the prostate-specific antigen (PSA) test to detect prostate cancer
- · conducted studies that helped gain FDA approval of Gleevec, now a first line therapy for chronic myeloid leukemia (CML).

THE STAGES OF CLINICAL TRIALS

Most clinical trials involve testing a potential new drug. Each study progresses in an orderly series of steps called phases. This allows researchers to ask and answer questions in a way that gives reliable results while protecting patients. Clinical trials usually include three phases.

PHASE I STUDIES...

are the first step in testing a new drug or intervention in people. Researchers evaluate what dose is safe and how it should be given.

PHASE II STUDIES...

continue to test the safety of the drug or intervention and evaluate how well it works. Phase II studies often focus on a particular type of cancer.

PHASE III STUDIES...

compare a new drug or intervention with the current standard. Phase III studies may include hundreds of people across the country.

Learn what our patients have to say about their www.RoswellPark.org/TrialJourney Learn what our patients have to say about their experience participating in a clinical trial at Roswell Park.