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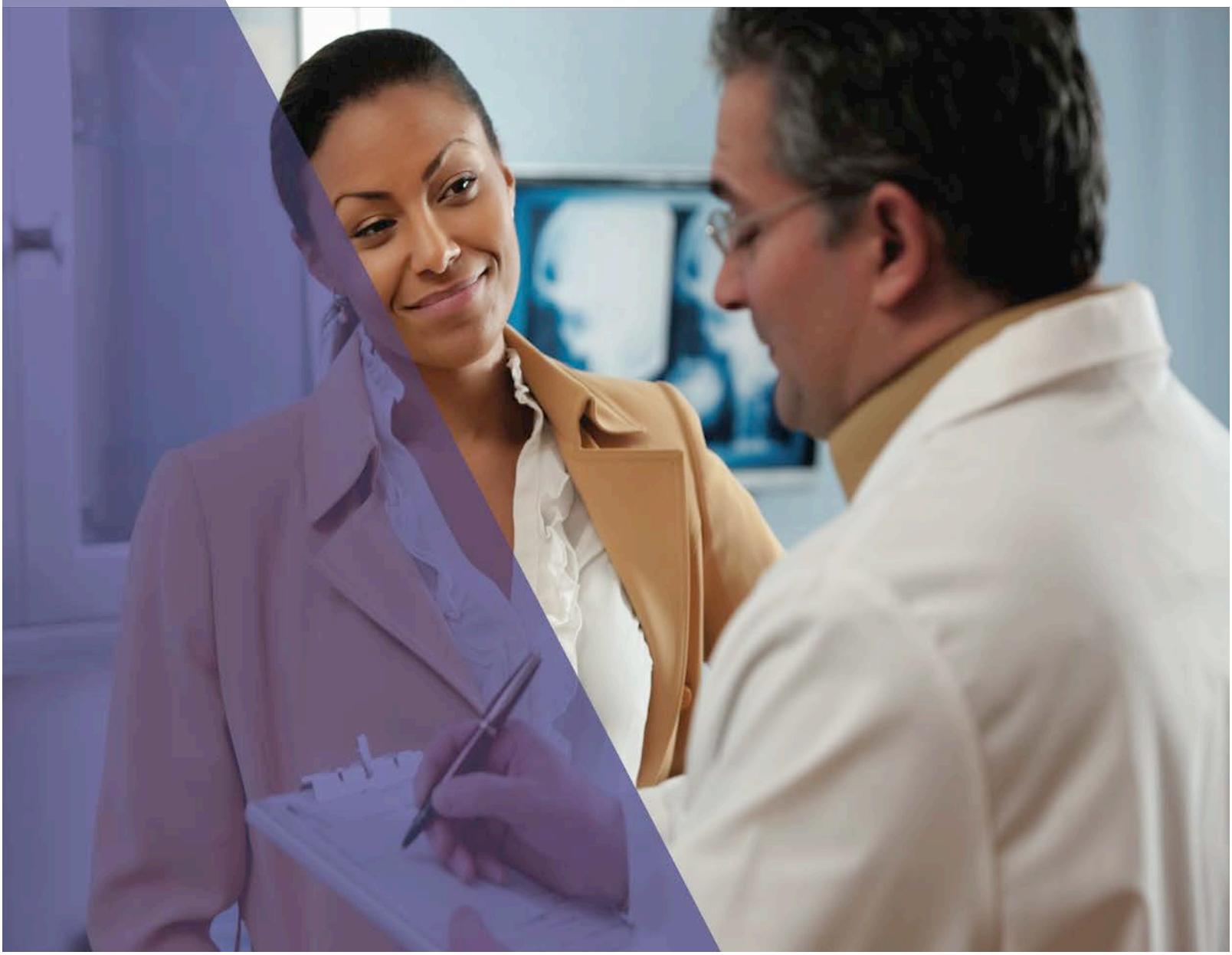
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

A Patient's Guide to Clinical Trials

Northwestern Memorial Hospital and Robert H. Lurie Comprehensive Cancer Center



All of today's standard drugs to treat cancer were once tested as part of a clinical trial

Clinical trials are at the core of what we do on our mission to end cancer. They are important because they provide researchers information about cancer that helps in the discovery of new therapies that treat or prevent cancer. New drugs are required to be tested in a clinical trial, to ensure they are safe and effective. To better understand clinical trials and the misconceptions we have outlined information below.

What is a clinical trial?

Clinical trials are medical research studies that:

- Test the safety and effectiveness of a new drug or combination of drugs
- Attempt to answer scientific questions about cancer

Other terms for clinical trial include,

Clinical trials are broken up into phases

Clinical trials are conducted in a series of steps called phases, each answering a separate research question.

Phase I Clinical Trials determine the safest dose of study drug a patient can receive. Patients start taking the study drug at a specific dose level, and are monitored closely for side effects. If no patients experience unacceptable side effects, the dose is increased to another specified level. This process is called 'dose escalation' and continues until the maximum safest dose is achieved.

Although the treatment in phase I trials may be effective at treating the cancer, this is not the main objective of a phase I trial.

Phase II Clinical Trials determine if a study drug works, how well it works and continue to monitor side effects for ongoing safety.

Phase III Clinical Trials compare the study drug with the standard-of-care for that cancer. In order for the FDA to approve a new drug, research is required to prove that it is effective against cancer, as well as safe.

Who can participate?

All clinical trials have safety guidelines for eligibility that patients must meet before they enroll in any given study. These criteria help ensure all patients are similar, so the results of the trial are reliable. Additionally, eligibility criteria make sure patients are healthy enough to participate in a clinical trial.

Examples criteria could include:

- Age
- Diagnosis
- Medical history
- Current health status

Who pays for the cost of clinical trials?

The affordable care act (ACA) requires most insurance companies to provide coverage of routine costs associated with a clinical trial.

Routine costs include any drugs or services needed while participating in a clinical trial that the insurer would normally cover, even if you were not participating in a trial.

Research costs include any test, drug or service that is outside of routine care. Research costs are the responsibility of the clinical trial sponsor.

How do I enroll into a clinical trial?

If it is determined that you are eligible for a clinical trial, a member of the study team will discuss the clinical trial in detail with you. This detailed conversation is part of the informed consent process.

You will receive information about the study drug, benefits to participating as well as any disadvantages. Your doctor or a member of the study team will explain why you are candidate for a clinical trial, why the trial is being conducted, and other treatment options available.

The informed consent process gives you an opportunity to think carefully about all treatment options and discuss with family members, before agreeing to participate.

For more information about Clinical Trials at the Lurie Cancer Center, please contact our dedicated Clinical Research Recruitment and Education Specialist at:

312.695.1102 or email inquires to: **cancertrials@northwestern.edu**