# PARTICIPATING IN A CLINICAL TRIAL: WHAT YOU NEED TO KNOW



Program Resource Guide

The Benefits of Joining a Clinical Trial	Questions to Ask About Clinical Trial Participation
<ul> <li>Helping current and future patients</li> <li>Learning more about a therapy and good practices for the future</li> <li>Gaining access to a new therapy that might not be available otherwise</li> <li>Personalized care and closer monitoring</li> </ul>	<ul> <li>What is the therapy being studied?</li> <li>What is the alternative?</li> <li>What are the eligibility criteria? Do I qualify?</li> <li>What are the logistics? Location, treatment schedule, etc.?</li> <li>What is the cost of joining the trial?</li> </ul>

#### **Phases of Clinical Trials**

- **Phase I**: The goal is to test the safety of the drug, finding the appropriate dose that produces the fewest side effects.
- Phase II: Further assesses the safety of the drug and the effectiveness of the treatment.
- **Phase III:** Compares the efficacy of the new treatment to the standard-of-care treatment.
- Phase IV: Study that looks at drugs that have already been approved to get additional safety
  information and to learn more about long-term benefits and side effects.

### **Types of Clinical Trials**

**Controlled Clinical Trial:** Study that includes a control (comparison) group in which the control group receives a treatment, no treatment, or a placebo.

**Double-Blind Study:** Clinical trial in which neither the participants nor the researcher knows which intervention the participants are receiving until the end of the clinical trial, reducing the likelihood of biased results.

**Observational Study:** A study in which participants are observed or certain outcomes are measured. No treatment is administered, and there are no efforts to affect the study outcome.

**Randomized Clinical Trial:** Trial in which participants are randomly divided into separate groups that compare different treatments or other interventions. The randomization means that the groups will be similar so that treatment effectiveness they receive can be compared more fairly.

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### **Glossary Terms**

**Biopsy**: Removal of tissue from a specific area of the body for further examination.

**Immunotherapy:** Type of therapy that harnesses one's own immune system to help the body fight cancer, infection, and other diseases.

**Inclusion Criteria:** Requirements that must be met to be included in a clinical trial that ensure that the participants are like each other. These specific factors include age, type and stage of cancer, prior treatments, and general health.

**Informed Consent**: Provides a thorough explanation of the purpose of the research, including the role of the patient and how the trial will work.

Placebo: An inactive drug or treatment with no therapeutic benefit.

**Standard of Care**: An established guideline that is consensus among experts as the most appropriate and/or effective treatment for a specific type and stage of cancer.

### **Thank You to Our Program Collaborators**

CancerGRACE

**Lymphoma Research Foundation** 

**CLL Society** 

**National Blood Clot Alliance** 

KnowAML

**National Organization for Rare Disorders (NORD)** 

The Leukemia & Lymphoma Society

Leukemia Research Foundation

**Lung Cancer Research Foundation** 

**MPN Research Foundation** 

**Scientific Education Support** 

**Tigerlily Foundation** 

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