

Clinical Trial Phases	CLL Clinical Trial Resources
<p>Phase I: The goal is to test the safety of the drug, finding the appropriate dose that produces the fewest side effects.</p> <p>Phase II: Further assesses the safety of the drug and the effectiveness of the treatment.</p> <p>Phase III: Compares the efficacy of the new treatment to the standard-of-care treatment.</p> <p>Phase IV: Looks at drugs that have already been approved to get additional safety information and to learn more about long-term benefits and side effects.</p>	<ul style="list-style-type: none"> ▪ Clinicaltrials.gov ▪ The Leukemia & Lymphoma Society: lls.org ▪ Leukemia Research Foundation: leukemiarf.org ▪ Lymphoma Research Foundation: lymphoma.org ▪ National Organization for Rare Disorders (NORD): raredisease.org

Questions to Ask About a Clinical Trial

- What is the treatment approach used in the study and the purpose of the trial?
- What are the risks and benefits of participation?
- What are the financial costs, if any? Are there assistance programs to help?
- Where is the trial located and can be coordinated with your local institution? Or is transportation available?
- How often you will need to go to the trial site and how long will the trial last?

Glossary Terms

Health Insurance Portability and Accountability Act (HIPAA): A set of national rules that help protect the privacy of a patient's personal medical information, provide patients with access to their medical records, and help people get health insurance for themselves and their family members.

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

Institutional Review Board (IRB): Committees that ensure that the risks of trial participation are reduced and outweighed by potential benefits in order to protect the rights and safety of research participants. Most clinical trials, but not all, in the United States are approved and monitored by an IRB both before the research starts and as it proceeds.



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

Protocol: The written description of a clinical study that includes the objectives, design, and methods. The protocol may also include scientific background and statistical information that pertains to the study.

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.

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.

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