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CONTENTS

CLL CLINICAL TRIALS

Goals of Clinical Trials
Types of Treatments Used in a Clinical Trial
Other Clinical Trials That Might be Right for You
Clinical Trials and Phases

CLL CLINICAL TRIAL PATIENT PROFILES

Overcoming Known Disparities and Access for CLL Patients
Chronic Lymphocytic Leukemia: Shirley’s Clinical Trial Profile
Chronic Lymphocytic Leukemia: Fran’s Clinical Trial Profile
Chronic Lymphocytic Leukemia: Adrian’s Clinical Trial Profile
Chronic Lymphocytic Leukemia: Dierdre’s Clinical Trial Profile

CLL CLINICAL TRIAL ACCESS AND RESOURCES

What Should CLL Patients Know About Clinical Trial Treatment Options?
CLL Clinical Trials Explained
Clinical Trial Resources
Understanding Clinical Trials: A Jargon Buster Guide

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WHAT ARE THE GOALS OF CLL CLINICAL TRIALS?

- Create truly curative therapies
- Develop therapies that can work when others have failed
- Decrease the side effects of treatment

TIPS FOR LEARNING ABOUT & FINDING CLINICAL TRIALS

- Know the stage of your CLL and obtain a copy of your pathology report
- Learn about eligibility criteria such as age and physical fitness
- See if there are financial resources that can help assist with travel and other costs
- Ask what the risks are to participating
WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

New Targeted Treatments - specific new drug therapies under study in clinical trials for people with CLL include:

- Ibrutinib (Imbruvica)
- Acalabrutinib (Calquence)
- Zanubrutinib (BGB-3111)
- Entospletinib (GS-9973)
- Tirabrutinib (ONO-4059 or GS-4059)
- Duvelisib (Copiktra)
- Umbralisib (TGR-1202)

Kinase Inhibitor Therapy - some types of cancer can be treated by kinase inhibitor drugs that target specific enzymes within the cancer cells that are involved in cell growth and death.

These drugs may be associated with fewer side effects than traditional chemotherapy agents.
WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL? (CONT.)

Monoclonal Antibodies
- Ofatumumab (Arzerra)
- Cirmtuzumab (UC-961)
- Obinutuzumab (Gazyva)
- Ublituximab (TG-1101)

Combinations of Antibodies with Other Targeted Drugs Being Investigated in Clinical Trials
- Combinations with immunomodulatory drugs
- Combination regimens of 3 or 4 drugs
- Combinations with venetoclax (Venclexta)

Checkpoint Inhibitors
- Nivolumab (Opdivo)
- Pembrolizumab (Keytruda)
OTHER CLINICAL TRIALS THAT MIGHT BE RIGHT FOR YOU

National Veteran Affairs Tumor Registry Study:
Exposure to Agent Orange has been associated with the development of CLL.

This multi-center, retrospective study focused on assessing the impact of Agent Orange exposure on the prognosis and management of CLL, using data from the National Veteran Affairs Tumor Registry.

According to the study’s findings, exposure to Agent Orange was not associated with either unfavorable prognostic factors or shortened survival in the large veteran population examined.
OTHER CLINICAL TRIALS THAT MIGHT BE RIGHT FOR YOU

**CLL Natural History Study**: helps researchers understand how CLL cells behave, which ultimately should help to develop new and better treatments for CLL patients.

Applying new technologies to investigate the molecular basis and clinical indicators of CLL and small lymphocytic lymphoma (SLL) can clarify processes involved in disease progression and possibly lead to the discovery of targeted treatments.

Patients may qualify for this clinical trial if they have never received treatment for their CLL.
Planting the seed - In Phase I trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Laying down roots - In Phase II trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

Preparing for harvest - In Phase III trials, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, & collect information that will allow the drug or treatment to be used safely.

Expanding the yield - In Phase IV trials, studies look at real-world experience over a long time and provide additional information on the drug’s risks, benefits, and optimal use.
For cancer patients, multiple studies have shown that there are some known barriers to equitable access to care. The overall clinical trial participation rate is only about 5 percent of adult cancer patients.

Some of the disparities show lower clinical trial participation rates for adolescent and young patients, patients over age 65, women in non-sex-specific cancers, and patients who earn $50,000 or less annually.

And though study results were somewhat mixed about whether participation rates have increased for Black, Indigenous, and People of Color (BIPOC) communities, it’s vital for BIPOC patients to increase their clinical trial participation rates as the percentages of BIPOC populations continue to rise in the overall U.S. population.

CLL clinical trial participants sharing their experiences helps to increase education about clinical trials.
To increase CLL clinical trial participation for underrepresented groups, there are several strategies to improve rates.

These strategies include:

- Starting discussions about clinical trials early in the patient journey, beginning with diagnosis and continuing to discuss throughout their testing process up until discussions start about treatment decisions.
- Making special efforts to connect adolescent CLL patients and female CLL patients with advocates targeted to their underrepresented age or gender to help patients feel more connected and trusting about clinical trials.
- Connecting non-native English speakers to translators early in their CLL journey to ensure patients understand clinical trial options.
- Continuing and extending reimbursement of food and transportation costs as part of clinical trial participation.
• CLL clinical trial participants sharing their experiences about clinical trials to increase education about trials.
• Patient advocacy websites and other resources including clinical trials as part of their foundational content for patients and caregivers.
• Continuing telemedicine as a viable option for initial entry into CLL clinical trials.

Educating CLL patients about clinical trials is an important piece of continuing effective clinical trials. If efforts can continue to reach CLL patients who are underrepresented in clinical trials, these efforts will help to improve care for CLL patients receiving care currently and for those who will need treatment years in the future.

As researchers receive more data on the CLL treatments under study, CLL treatments will continue to be refined for subtypes and other factors for optimal CLL care and quality of life for each patient.

Joseph M. Unger, PhD, Elise Cook, MD, Eric Tai, MD, and Archie Bleyer, MD; The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies; ASCO Educational Book.
"In my late 30s, I started feeling really fatigued. As a mother of a 5-year-old at the time, I thought perhaps trying to keep up was zapping my energy, but it turned out I had chronic lymphocytic leukemia. My medical team informed me that my CLL was particularly aggressive and rare, and I was not the typical case. I was fortunate to connect to a well-respected CLL expert who told me there was no blueprint and that I would need to enter a clinical trial."
"In my late 50s, I was diagnosed with chronic lymphocytic leukemia during a routine blood test as part of my military testing when I worked as a hospital nurse. My care included multiple CLL treatments, I just think that clinical trials play just such an important role in the future of all of medicine, but particularly CLL we've come such a distance in my 20 years that we would have never come had we not had people that came before me, in clinical trials."
"A clinical trial is an opportunity for you as an individual to get a treatment that may well not be available to you outside of the trial, and so that can be a benefit to you and also gives you the opportunity to have extra care potentially. But also it's an opportunity for us to give back, and I think for society as a whole, it's really important that patients are willing to volunteer so that we can get new medicines. Because without clinical trials we’ll never get new medicines, we'll just be stuck with the old ones."
"I think everyone needs to decide for themselves and think, you know, 'What's best for me?'

Is a medical trial best for me or just having normal treatment?' Everybody is different. Everybody's CLL is different."
What do chronic lymphocytic leukemia (CLL) patients need to know about clinical trial treatment options? Dr. Matthew Davids explains how clinical trials fit into the array of CLL treatments, the benefits of speaking to a CLL specialist, and online resources for finding clinical trials.

Dr. Matthew Davids is Director of Clinical Research in the Division of Lymphoma at Dana-Farber Cancer Institute.
What are the phases of clinical trials in chronic lymphocytic leukemia (CLL), and what happens during each phase?

Expert Dr. Anthony Mato explains the phases, criteria for trial selection, and addresses patient fears.

Dr. Anthony Mato is Director of the CLL Program at Memorial Sloan Kettering Cancer Center.
Clinical Trial Resources

Clinicaltrials.gov
Provides information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The website is maintained by the National Library of Medicine at the National Institutes of Health.

Each clinical trial record presents summary information about a study protocol and includes the following:

- Disease or condition
- Intervention (for example, the medical product, behavior, or procedure being studied)
- Title, description, and design of the study
- Requirements for participation (eligibility criteria)
- Locations where the study is being conducted
- Contact information for the study locations
NIH National Cancer Institute
Contact: Call 1-800-422-6237, live chat through LiveHelp or email NCIinfo@nih.gov

Search portal to find National Cancer Institute (NCI)-supported clinical trials. Search by cancer type or keyword, your age (to determine which trials you could be eligible for) or U.S. ZIP code

Contact: 1-800-887-0639; email info@clinicalconnection.com

Founded by a team of medical researchers whose goal has been to efficiently connect patients with clinical trial opportunities that are relevant and timely. Options to create a free member account to be notified when clinical trials that match your health interests become available in your area.

Search for trials (both in U.S. and internally) by ZIP code, keyword, or distance (select distance ranges starting from within 5 miles up to over 250 miles)
CISCRP
(Center for Information and Study on Clinical Research Participation)
Contact: 877-MED-HERO (633-4376) or info@ciscrp.org

Provides education and information about clinical trials. Search Clinical Trials is a free service designed to help people find clinical trials that are relevant to their needs.

CISCRP staff will work with you to understand your options and will help you find local clinical trials in your community, or as far as you would be comfortable traveling.

Antidote
1-888-509-1308 (US) or +44 808-196-0665 (UK)
Email: hello@antidote.me

Search for clinical trials by condition, city or ZIP code, age, and gender. Receive list of clinical trials that could be a match for you by answering series of questions. Watch educational webinars and patient stories.
The fund provides financial assistance to patients diagnosed with a blood cancer, like CLL who are being evaluated to receive CAR T-cell therapy as either standard treatment or a clinical trial.

For more information, visit:
https://www.lls.org/support/financial-support/pre-car-t-cell-therapy-travel-assistance-program

Lazarex Cancer Foundation
Contact: 877-866-9523 or 925-820-4517
Other language(s): Spanish, Mandarin, Korean

Helps cancer patients navigate clinical trial options by offering financial assistance (such as lodging and transportation costs) for participation in FDA-approved clinical trials; call for eligibility details. Also provides community outreach and education.
21st Century C.A.R.E.
Get immediate financial assistance for incidental expenses related to active cancer treatments. Must be referred by a physician to be considered for assistance.

Applications are processed without delay. Once the application is approved, then you are eligible for financial assistance for incidental expenses related to: transportation to and from treatments, follow-up visits related to cancer-care, childcare during treatment, temporary housing due to geographical distance from the treatment center, medical supplies, and much more.

Medicare and the National Cancer Institute provides information on Medicare coverage for clinical trials. Contact: 1–800–633–4227 or 1–877–486–2048 for hearing impaired

CenterWatch offers online tools to:
- Search clinical trials
- Receive email notifications about specific clinical trials
- Review results from completed clinical trials
- Search drug information
- Learn about the informed consent process
- Read an overview of the clinical trials process
- Find disease-specific health associations and other educational resources
When it comes to cancer treatment, you or a loved one may be considering participating in a clinical trial as a treatment option. Clinical trials are designed to evaluate the safety and effectiveness of a treatment. They may involve researchers administering drugs, taking blood or tissue samples, or checking the progress of patients as they take a treatment, according to a study’s protocol.

Learning about clinical trials can be a steep learning curve – not the least because the process comes with a lot of new terms, acronyms, and jargon. To help you, we’ve put together this list of the most common terms you will find when you are researching clinical trial information. This is not an exhaustive list, but it is a helpful starting point. At the end of this article, you will see links to find more information.
ADVERSE EFFECTS (AE)
Also called Adverse Events, or Adverse Drug Reaction, AEs are any harmful event experienced by a person while they are having a drug or any other treatment or intervention. In clinical trials, researchers must always report adverse events, regardless of whether or not the event is suspected to be related to or caused by the drug, treatment, or intervention.

ARM
Subsection of people within a study who have a particular intervention.
BIAS
Bias is an error that distorts the objectivity of a study. It can arise if a researcher doesn’t adhere to rigorous standards in designing the study, selecting the subjects, administering the treatments, analyzing the data, or reporting and interpreting the study results. It can also result from circumstances beyond a researcher’s control, as when there is an uneven distribution of some characteristic between groups as a result of randomization.

BLINDING
Blinding is a method of controlling for bias in a study by ensuring that those involved are unable to tell if they are in an intervention or control group, so they cannot influence the results. In a single-blind study, patients do not know whether they are receiving the active drug or a placebo. In a double-blind study, neither the patients nor the persons administering the treatments know which patients are receiving the active drug.
COMPARATOR
When a treatment for a specific medical condition already exists, it would be unethical to do a randomized controlled trial that would require some participants to be given an ineffective substitute. In this case, new treatments are tested against the best existing treatment, (i.e., a comparator). The comparator can also be no intervention (for example, best supportive care).

COMPLETED
A trial is considered completed when trial participants are no longer being examined or treated (i.e., no longer in follow-up); the database has been "locked" and records have been archived.

CONTROL
A group of people in a study who do not have the intervention or test being studied. Instead, they may have the standard intervention (sometimes called "usual care") or a dummy intervention (placebo). The results for the control group are compared with those for a group having the intervention being tested. The aim is to check for any differences. The people in the control group should be as similar as possible to those in the intervention group, to make it as easy as possible to detect any effects due to the intervention.
EFFICACY

How beneficial a treatment is under ideal conditions (for example, in a laboratory), compared with doing nothing or opting for another type of care.

A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

ELIGIBILITY CRITERIA/INCLUSION AND EXCLUSION CRITERIA

Eligibility criteria ensures patients enrolling in a clinical trial share similar characteristics (e.g., gender, age, medications, disease type, and status) so that the results of the study are more likely due to the treatment received rather than other factors.

FOLLOW-UP

Observation over a period of time of participants enrolled in a trial to observe changes in health status.
INFORMED CONSENT
A process (by means of a written informed consent form) by which a participant voluntarily agrees to take part in a trial, having been informed of the possible benefits, risks and side effects associated with participating in the study.

INTERVENTION
The treatment (e.g., a drug, surgical procedure, or diagnostic test) being researched. The intervention group consists of the study participants that have been randomly assigned to receive the treatment.

INVESTIGATOR
A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (PI).

MULTICENTER TRIAL
A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
NUMBER NEEDED TO TREAT (NNT)
The average number of patients who need to receive the treatment or other intervention for one of them to get the positive outcome in the time specified.

OUTCOME MEASURES
The impact that a test, treatment, or other intervention has on a person, group, or population.

PLACEBO
A fake (or dummy) treatment given to patients in the control group of a clinical trial. Placebos are indistinguishable from the actual treatment and used so that the subjects in the control group are unable to tell who is receiving the active drug or treatment. Using placebos prevents bias in judging the effects of the medical intervention being tested.

POPULATION
A group of people with a common link, such as the same medical condition or living in the same area or sharing the same characteristics. The population for a clinical trial is all the people the test or treatment is designed to help.
PROTOCOL
A plan or set of steps that defines how something will be done. Before carrying out a research study, for example, the research protocol sets out what question is to be answered and how information will be collected and analyzed.

Randomized Controlled Trial (RCT)
A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug, treatment, or other intervention. One group has the intervention being tested; the other (the comparison or control group) has an alternative intervention, a placebo, or no intervention at all.

Participants are assigned to different groups without taking any similarities or differences between them into account. For example, it could involve using a computer-generated random sequence. RCTs are considered the most unbiased way of assessing the outcome of an intervention because each individual has the same chance of having the intervention.
RELIABILITY
The ability to get the same or similar result each time a study is repeated with a different population or group.

SAMPLE
People in a study recruited from part of the study’s target population. If they are recruited in an unbiased way, the results from the sample can be generalized to the target population as a whole.

SUBJECTS
In clinical trials, the people selected to take part are called subjects. The term applies to both those participants receiving the treatment being investigated and to those receiving a placebo or alternate treatment.

TRIAL SITE
The location where trial-related activities are conducted.