

THE LEUKEMIA & LYMPHOMA SOCIETY: HOW TO NAVIGATE THE MAZE OF CLINICAL TRIALS

Abbey Fueger, BA, BSN, RN

Clinical Trial Nurse Navigator
Clinical Trial Support Center



BASICS: CLINICAL TRIALS CAN FEEL LIKE NAVIGATING A MAZE










BASICS: WHAT IS A CLINICAL TRIAL?

Cancer clinical trials are:

-  Carefully controlled research studies to improve the care and treatment for cancer patients

Interventional trials:

-  Investigate ways to prevent the initial development of a disease
-  Study a new therapy, device, or a new use for an already approved therapy
-  Compare a new treatment with a standard treatment to find out which one works better and/or has fewer side effects
-  Improve quality of life
-  Increase the length of survival or length of disease-free survival

Observational trials:

-  Assess diseases in a specific group



BASICS: RISKS & BENEFITS OF CLINICAL TRIALS

Benefits

- 🔴 Contribution to the present and the future
- 🔴 Early access to new therapies
- 🔴 The drug(s) being studied is free
- 🔴 Access to specialized physicians
- 🔴 Followed closely

Risks

- 🔴 Possibility the treatment may not work
- 🔴 Unknown/fear of side effects
- 🔴 Randomized trials
 - Risk of being in the standard of care arm
- 🔴 Increased time away from home, work and family



CLINICAL TRIAL MYTHS

🔴 I can only join a clinical trial if I have exhausted all other options

✓ Clinical trials are available throughout the disease process.

🔴 Clinical trials are not safe, and I will not benefit from them

✓ US clinical trials are designed to give patient the safest, potentially most effective clinical therapies.

🔴 I might get a placebo or a sugar pill instead of a real drug if I join a clinical trial

✓ Regulations require patients to know if placebo is involved as part of a trial. Placebos are rarely used in serious or life-threatening diseases.

🔴 Participation in clinical trials are free

✓ The drug that is being studied is free. Patient is responsible for standard of care therapy, admission to hospitals, physician visits and other associated costs.



BASICS: BARRIERS TO ENROLLMENT

Patient Barriers

- 🔴 Health Insurance/other financial constraints
- 🔴 Location of trial site(s)
- 🔴 Lack of awareness of opportunities
- 🔴 Fear and preference not to lose control of treatment decision-making
- 🔴 Complexity of access and stringency of trial participation
- 🔴 Other logistical factors

Physician Barriers

- 🔴 Lack of awareness of available trials outside of their center
- 🔴 Insufficient time to research trials
- 🔴 Ineffective patient identification/bias
- 🔴 Quality & variability of communication
- 🔴 Trial availability
- 🔴 Concern of “losing” patient to another center



WHERE DOES CLINICAL TRIAL ENROLLMENT STAND TODAY?

- 🔴 Clinical trials are the key step in advancing all cancer treatments
- 🔴 US participation in cancer clinical trials
 - 🔴 5% adults
 - 🔴 20% children
- 🔴 Only about 27% of cancer patients are eligible for available clinical trials*
- 🔴 20% of cancer clinical trials fail/close due to insufficient enrollment
- 🔴 The clinical trial landscape is complicated and can be overwhelming to navigate







WHAT'S NEXT FOR CLINICAL TRIALS?

- 🔴 Increasing diversity of clinical trial participants
 - 🔴 Modifying eligibility criteria to promote inclusion
 - 🔴 Promoting awareness of who participated in clinical trials
- 🔴 Reducing barriers to enrollment
 - 🔴 Increase flexibility and accessibility of trials





FINDING TRIALS: WHERE TO LOOK?

-  Your Healthcare Provider
-  Government Databases
-  Industry and For-Profit Companies
-  Patient Organizations



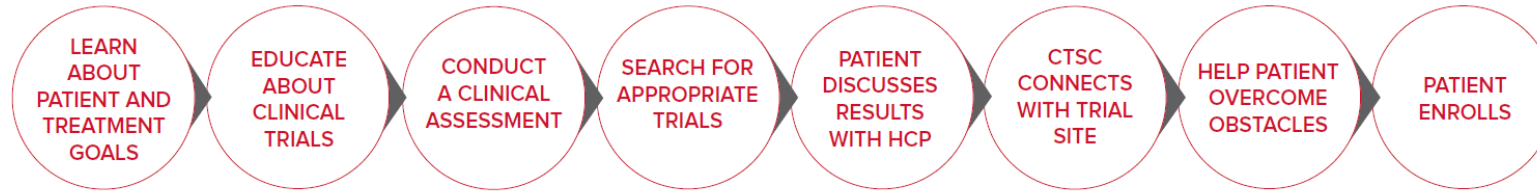
LLS COMMITMENT: PROVIDING RESOURCES TO HELP PATIENTS ACCESS CLINICAL TRIALS

- 🔴 Comprehensive patient navigation service
- 🔴 Highly trained nurse navigators complete nursing, psychosocial & educational assessments
- 🔴 Provide patient with individualized, patient-friendly list of appropriate clinical trials to discuss with health care team
- 🔴 Speak to sites, healthcare providers & industry regarding trials, addressing various barriers
- 🔴 Provide follow-up throughout the process
- 🔴 Personal connection



CLINICAL TRIAL SUPPORT CENTER (CTSC)

Process for Supporting Patients




What to expect during your initial call:



Get to know the patient

-  Discuss reasons for seeking treatment with a trial, address barriers to enrollment, and learn about the patient

Clinical Intake

-  Discuss prior treatments/response, current physical condition and past medical history that may impact eligibility for certain trials

Provide support and education

-  Help patient to understand the clinical trial process including the rights and obligations as a participant
-  Discuss clinical trial phases, demands, and trade-offs

CTSC CLINICAL TRIAL SEARCH RESULTS

The Leukemia and Lymphoma Society (LLS) National Research Registry


[NCT04806295](#) Phase **Not Specified** **Open**

The Leukemia and Lymphoma Society (LLS) has built a National Research Registry to evaluate real world experiences and medical outcomes for people with blood cancer, before, during, and after blood cancer treatments.

Significant Eligibility Requirements:

- Find additional information and link join the trial at <https://www.ciitizen.com/LLS/>

 **Lymphoma and Leukemia Society**
Rye Brook, NY 10573 **Open**

 Larry Saltzman, MD
844-696-7228 larry.saltzman@lls.org
Brian J Chadwick, BS RN
9144145788 chadwickbj@gmail.com

The Lymphoma and Leukemia Society COVID-19 Registry

[NCT04794387](#) Phase **Not Specified** **Open**


Participants in The Leukemia and Lymphoma Society (LLS) National Research Registry will be invited to participate in the LLS Covid-19 Registry to evaluate medical outcomes for people with blood cancer, who have been diagnosed with COVID-19, have received, or are planning to receive, a COVID-19 vaccination.

Significant Eligibility Requirements:

- People with blood cancer already participating in The Lymphoma and Leukemia National Research Registry

For additional information and to participate visit: <https://www.ciitizen.com/LLS/>

 **Lymphoma and Leukemia Society**
Rye Brook, NY 10573 **Open**

 Larry Saltzman, MD
844-696-7228 larry.saltzman@lls.org

A clinical trial is a carefully controlled research study conducted by doctors to improve the care and treatment of people with cancer or other illnesses. You can find more information at these links:

- [LLS booklet, Understanding Clinical Trials for Blood Cancers: LLS booklet, Understanding Clinical Trials for Blood Cancers](#)
- [LLS Clinical Trials Website](#)
- [Questions to Ask Your Healthcare Provider About Clinical Trials](#)



HERE TO HELP: CTSC PATIENT PROCESS



What to expect after the trial search:




CTSC will help guide the patient in their efforts to enroll in a trial.



CTSC nurse navigator can reach out to the site contact to find out the next steps for the patient to enroll.



Help address obstacles to enrollment.



CTSC nurse navigator can make referrals and help address obstacles related to travel and lodging.



Provide support.






CTSC nurse navigator is available for support and questions throughout the patient's experience in the trial.

CLINICAL TRIAL SUPPORT CENTER (CTSC) OUTCOMES FOR FISCAL YEAR 2021

- 9 CTSC nurse navigators assisted 1,019 patients
- Nurse navigators had over 9,800 interactions with patients, caregivers & medical professionals
- **20% of the 1,019 patients enrolled into a clinical trial***
- **Reasons patients did not enroll:**
 - Restrictive inclusion/exclusion criteria
 - Insurance restrictions
 - Health status rapidly deteriorated
 - Unable/unwilling to travel
 - Went onto SOC or off-label use



CLINICAL TRIAL SUPPORT CENTER (CTSC)

-  The goal of the CTSC is NOT to enroll every patient into a trial, rather to **increase the opportunities for participation by facilitating informed decision-making and minimizing logistical barriers** for the patient.
-  We **work in collaboration** with the patient's healthcare team to decide if a clinical trial is right for them.
-  Ultimately, we **educate, support and empower** patients to be active participants in, and have control over, their treatment decisions.



HOW TO ACCESS THE CLINICAL TRIAL SUPPORT CENTER (CTSC)

Call the Information Resource Center (IRC) [1-800-955-4572](tel:1-800-955-4572)

Patient or caregivers can complete an online referral form at:
<https://www.lls.org/navigation>

ASH physicians can access the portal at:

<https://www.hematology.org/clinicaltrialnavigation/>

Other Healthcare Providers can complete a referral form at:

<https://www.lls.org/article/clinical-trial-support-center-ctsc-portal-for-healthcare-providers>

