

THE IMPORTANCE OF CLINICAL TRIALS TO TREAT BLOOD CANCER

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LEARNING OBJECTIVES



SUMMARIZE
 THE BASICS OF
 CLINICAL TRIALS



EXPLAIN THE
 DEVELOPMENT AND
 PHASES OF
 CLINICAL TRIALS



DESCRIBE
 DISPARITIES IN
 CLINICAL TRIALS



ENGAGE PATIENTS
 AND CAREGIVERS IN
 DISCUSSION ON
 RISKS, BENEFITS,
 MYTHS AND COSTS
 OF CLINICAL TRIALS



EXPLAIN HOW LLS
 CAN HELP LOCATE
 CLINICAL TRIALS
 THAT MAY BE RIGHT
 FOR YOUR
 PATIENTS

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The **BASICS** of clinical trials



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BASICS: KEY STEPS IN DRUG DEVELOPMENT

Initial discovery &
development of new
drug in lab

NDA submitted to
FDA

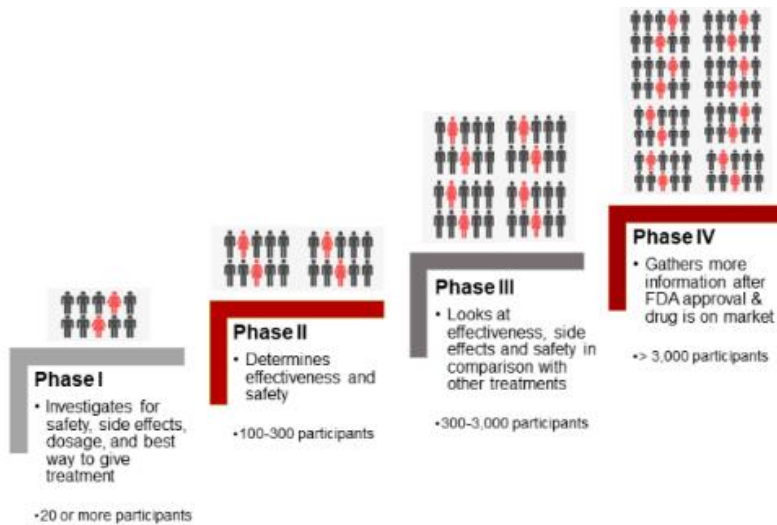
Studied in people in
carefully controlled
clinical trials



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BASICS: PHASES OF CLINICAL TRIALS

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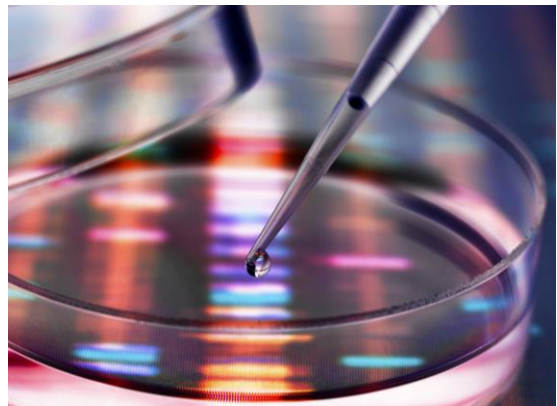


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BASICS: KEY STATS ABOUT CLINICAL TRIALS

- Cancer clinical trials are 40-50% of all trials conducted in the United States
- Only 5% of adult patients and >50% of children in the U.S. participate in cancer clinical trials
- 20% of cancer clinical trials fail/close due to insufficient enrollment
- Only 27% of cancer patients have the option to enroll in a local clinical trial

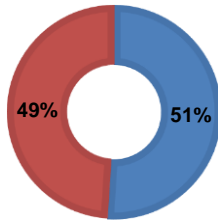


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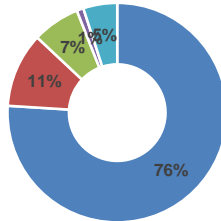
BASICS: CLINICAL TRIAL DISPARITIES

Sex Distribution



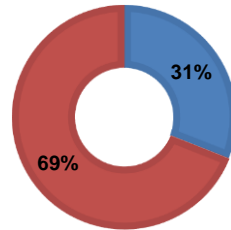
- Female
- Male

Race Distribution



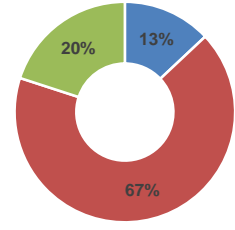
- White
- Asian
- Black or African American
- American Indian or Alaska Native
- Other

Age Distribution



- ≥65 years
- <less than 65 years

Ethnicity Distribution



- Hispanic or Latino
- Not Hispanic Latino
- Missing

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BASICS: WHAT IS BEING DONE ABOUT DISPARITIES?



The Patient Protection and Affordable Care Act (ACA) enacted

Medicare coverage

Medicaid coverage

Easing of stringent eligibility requirements

Well designed outreach programs

Sponsor and other support of financial impact



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BASICS: RISKS AND BENEFITS OF CLINICAL TRIALS

Benefits

- Contribution to future patients
- Early access to new therapies
- The drug(s) being studied is free
- Access to physicians with extensive experience
- Close monitoring to ensure safety

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



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BASICS: 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**
 - ✓ Process that starts in the lab and is regulated by FDA in the USA.
- **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. Placebos are rarely used in serious or life-threatening diseases.
- **Clinical trials are free**
 - ✓ The drug that is being studied is free. Patient is responsible for standard of care therapy, admission to hospitals, physicians and other associated costs.



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BASICS: UNDERSTANDING THE TRUE FINANCIAL COST

Sponsor	Insurance Carrier (Private, Medicare or Medicaid)	Patient
<ul style="list-style-type: none"> Cost of experimental treatment and treatment administration 	<ul style="list-style-type: none"> Standard of care tests and treatment 	<ul style="list-style-type: none"> Co-pays, deductibles, and out-of-network costs
<ul style="list-style-type: none"> Travel and lodging are sometimes included This is study specific, always ask 	<ul style="list-style-type: none"> Costs of complications of the treatment 	<ul style="list-style-type: none"> Travel or lodging for patient and/or caregiver along with food and other incidental costs.
<ul style="list-style-type: none"> Extra tests, interventions or office visits required by the trial 	<ul style="list-style-type: none"> There may be limitations related to Phase 1 trials, out of network trials, or out of state trials 	<ul style="list-style-type: none"> Loss of employment/ income and other costs such as child-care, elder care, pet care



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BASICS: UNDERSTANDING COMMON BARRIERS

Patient Barriers

- Health insurance coverage and other financial constraints
- Location of trial site(s)
- Fear of participation
- The lack of awareness of opportunities to participate
- Complexity of access, eligibility, and stringency of trial participation

Physician Barriers

- Lack of awareness of opportunities outside of home institution
- Insufficient time to research available trials outside of home institution
- Fear of "losing" their patient to another center
- Quality and variability of communication with patients
- Ineffective patient identification/bias



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BASICS: FINDING CLINICAL TRIALS

Information about clinical trials is out there but.....



.....finding trials that are right for your patient can be exasperating!



The **CTSC** can **HELP**



HERE TO HELP: THE CLINICAL TRIAL SUPPORT CENTER TEAM



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MSN, RN, CHPN, CNL
Clinical Trial Nurse Navigator

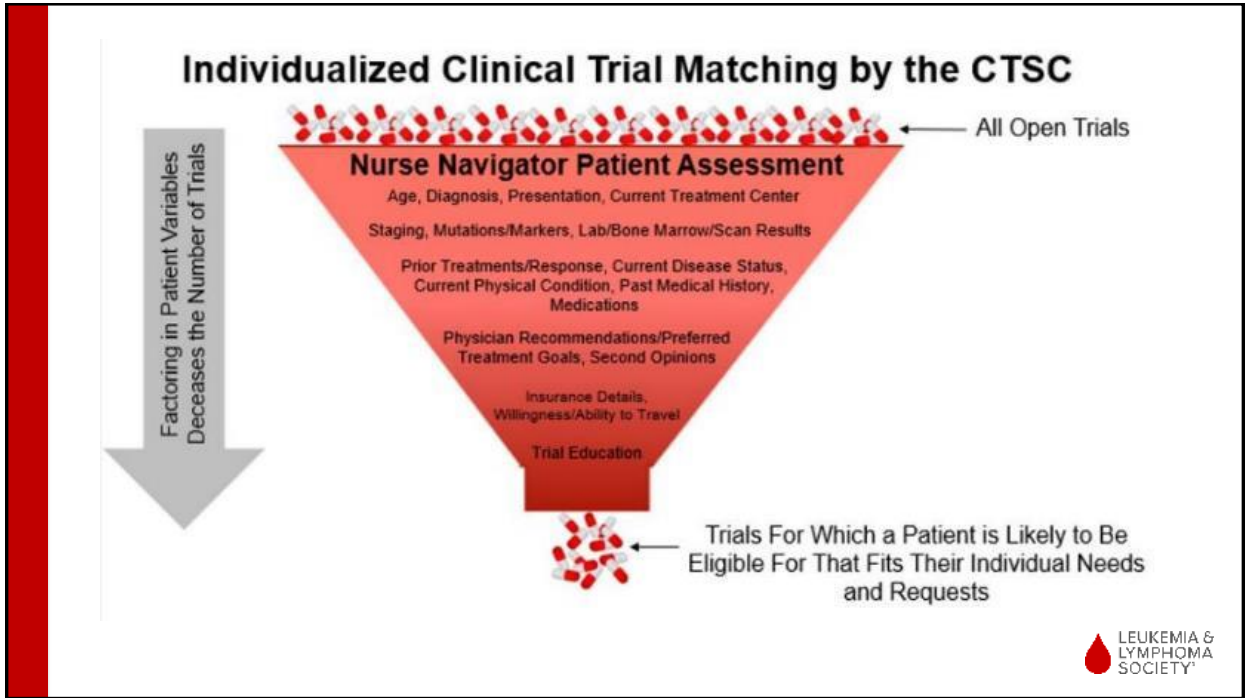


Christen Hawthorne
RN, BSN, BMT-CN
Clinical Trial Nurse Navigator

HERE TO HELP: LLS COMMITMENT

CTSC PROCESS FOR SUPPORTING PATIENTS





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HERE TO HELP: CTSC CLINICAL TRIAL SEARCH RESULTS

The results of the clinical trial search are below. I have provided contact information for each trial, a brief description and when appropriate, **specific eligibility requirements that are important to consider**. If you are interested in any of these trials, I am happy to reach out on your behalf to learn more about your potential eligibility. You will see in green where I have highlighted **eligibility requirements** to discuss whether or not the trial accepts patients with CLL involvement and I have not received a response yet. Once I do receive a response, I will update you accordingly. **CLL-T trials are highlighted with an orange bar on the left hand side.** Over time trials may change, there may be additional trials open, or some may have closed. We can update this search at any time. Please let me know if you would like an updated or expanded search for you any time. I will be happy to do so for you. If you need a different search, i.e. treatment naive CLL after your doctors appointments, I am also happy to do this for you. Below I have also included information on CLL, CLL-T therapy, and clinical trials.

To access more information about a particular trial, click on the **trial NCT number**. This will bring you to the individual trial page. Here you will find a list of centers where the trial is taking place and some general information about the protocol. If you have any questions about the search information, please let me know. As I mentioned, I can help facilitate communication with the sites/MD regarding enrollment or any trial questions you may have.

Seleneor and Ibrutinib in Treating Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia or Aggressive Non-Hodgkin Lymphoma
 NCT02088662 Phase II Open

This phase II trial studies the side effects and best dose of seleneor when given together with ibrutinib in treating patients with chronic lymphocytic leukemia or aggressive non-hodgkin lymphoma that has returned after a period of improvement or does not respond to treatment.

Significant eligibility requirements:

- CLL with at least one prior therapy that is relapsed or refractory.
- ECOG 0-2.
- Patients with known CNS involvement of CLL or lymphoma are excluded but patients with history of CNS CLL or lymphoma are eligible for the trial.**

Hamman Cancer Institute
261 Lake City Dr #1112 (link)
The Ohio State Comprehensive Cancer Center
1-800-393-6336
Email: OSUCCC2016@osu.edu
Arthur C. James Cancer Hospital and Solove Research Institute at Ohio State University Medical Center
Columbus, OH 43210 (link)
The Ohio State Comprehensive Cancer Center
1-800-393-6336
Email: OSUCCC2016@osu.edu

Study of Immunotherapy in Combination With Ublituximab and Umbralisib in Patients With Relapsed-refractory CLL or Richter's Transformation
 NCT03580366 Phase I/II Open

The purpose of this study is to evaluate the safety and effectiveness of targeted immunotherapy in combination with ublituximab and umbralisib, in patients with advanced CLL or Richter's transformation.

Significant eligibility requirements:

- Confirmed diagnosis of B-cell CLL that is refractory or relapsed after at least 1 prior treatment regimen
- ECOG 0-2.

Highlighted in orange regarding whether CNS involvement is allowed on this trial.

University of Pennsylvania
Philadelphia, PA 19104 (link)
Texas A&M Health System
Texas A&M Health System
Email: tanya.stevan@texasaam.edu

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The **IMPACT** of the **CTSC Nurse Navigators**



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CTSC IMPACT: HCP STORY



- ◆ Oncologist filled in online referral for CTSC support for a young adult with r/r T-cell ALL
- ◆ CTSC NN emailed back and forth with oncologist to get assessment details to provide most personalized search possible
- ◆ NN connected with patient and his family to do nursing assessment and provide CT education and LLS support
- ◆ NN reached out to trial sponsors regarding slot availability, screening process, travel and lodging reimbursement
- ◆ NN provided detailed information to oncologist and patient
- ◆ Trial was identified and plan for bridging therapy was made to hopefully get into the trial when a slot was available
- ◆ NN remains available to oncologist, patient and his caregiver as needed



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CTSC IMPACT: HCP STORY



“Hi Kelly, thank you so much, that is super helpful. I’m pretty sure I can bridge him for another two months until he gets his slot in Nov. This LLS service is amazing.”

Steven Tsai MD, PhD



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“ I have been in contact with social workers and clinical trial navigators at LLS and can hardly believe how accessible, knowledgeable, helpful, and genuinely caring they have been. The expertise at LLS has saved me hours of research and countless sleepless nights!”

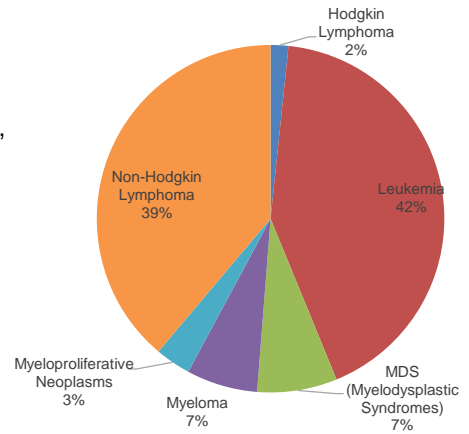
— Julie, lymphoma patient



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CTSC OUTCOMES: FISCAL YEAR 2023

- 10 CTSC nurse navigators assisted a total of 1,345 patients
- Nurse navigators had over 10,580 interactions with all patients, caregivers & medical professionals
- **23% of eligible 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



Disease Category Breakdown of Patients That Entered Into A Clinical Trial



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CLINICAL TRIAL SUPPORT CENTER

- The goal of the CTSC is NOT to enroll every patient into a trial, but 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.



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HOW TO ACCESS THE CLINICAL TRIAL SUPPORT CENTER (CTSC)

Call the Information Resource Center (IRC) **1-800-955-4572**

Patient or caregivers can complete an online referral form at:
www.LLS.org/CTSCreferral

Healthcare Providers can complete a referral form at:
<https://www.lls.org/article/clinical-trial-support-center-ctsc-portal-for-healthcare-providers>

Email the CTSC directly with questions at: CTSC@LLS.org



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Healthcare Provider Resources

- CE and CME Programs
 - www.LLS.org/CE
- Podcast: Treating Blood Cancers
 - www.LLS.org/HCPpodcast
- Staying Connected: Facilitating the Learning Experience During & After Cancer Treatment - www.LLS.org/StayingConnected
 - online course to educate school personnel on the effects of childhood and AYA cancer treatment to improve the learning experience for students
- HCP Fact Sheets
 - www.LLS.org/HCPbooklets
- HCP Videos
 - www.LLS.org/HCPvideos



800-955-4572 or www.LLS.org/CE



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**THANK YOU
QUESTIONS?**

EMAIL: CTSC@LLS.ORG

We have one goal: A world without blood cancers



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