



**The Leukemia & Lymphoma Society:
Help in Choosing a Clinical Trial
IWMF Educational Forum
May 2018**

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Breakout Session Objectives

- Myths about clinical trials
- How to find clinical trials
- How LLS can help locate clinical trials that may be right for you
- What are your rights around clinical trials





Barriers To Enrollment

Patient Barriers

Fear of being a “guinea pig”

Misunderstanding the role of placebos in oncology

Lack of awareness of opportunities

Complexity of access and stringency of trial participation

Confusing to find a clinical trial





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 US
- 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.



Clinical Trial Phases

How do clinical trials work?

Phase I investigates for safety and side effects, dosage and best way to give treatment—includes 20 or more people

Phase II determines effectiveness and safety—typically includes fewer than 100 (but may include up to 300) people

Phase III looks at effectiveness, side effects and safety in comparison with other treatments—includes 100s to 1000s of people

Phase IV gathers more information after FDA approval & drug is on market



Payment

Sponsor	Insurance Carrier	Patient
Cost of treatment and treatment administration	Standard of care tests and treatment	Co-pays/Co-insurance, Deductibles, Out of Network Costs
Travel and lodging sometimes included—should always ask	Cost of complications of treatment	Travel and lodging for patient and/or caregiver
Extra tests, interventions or office visits required by trial	May or may not cover phase 1 trials	Food, incidentals
	May or may not cover trials that take place out of network or out of state	Loss of employment income for patient and/or caregiver
		Child care; pet boarding, home maintenance



Clinical Trial Protocols

Clinical trial protocols ensure that patients are closely monitored

- Patients get a lot of attention and support
- Patients are watched closely by their doctor, as well as other members of their medical team, to ensure their safety



Where Do I Find Clinical Trials?



Where Can I Find Clinical Trials?





- A web-based resource that provides access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.
- Maintained by the [National Library of Medicine](#) (NLM) at the [National Institutes of Health](#) (NIH)
- Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study.



ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 272,009 research studies in all 50 states and in 203 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

Saved Studies (14)

Recruitment status ⓘ

- Recruiting and not yet recruiting studies
 All studies

Condition or disease ⓘ (For example: breast cancer)

Waldenstrom Macroglobulinemia X

Other terms ⓘ (For example: NCT number, drug name, investigator name)

X

Country ⓘ

United States X

State ⓘ

X

City ⓘ

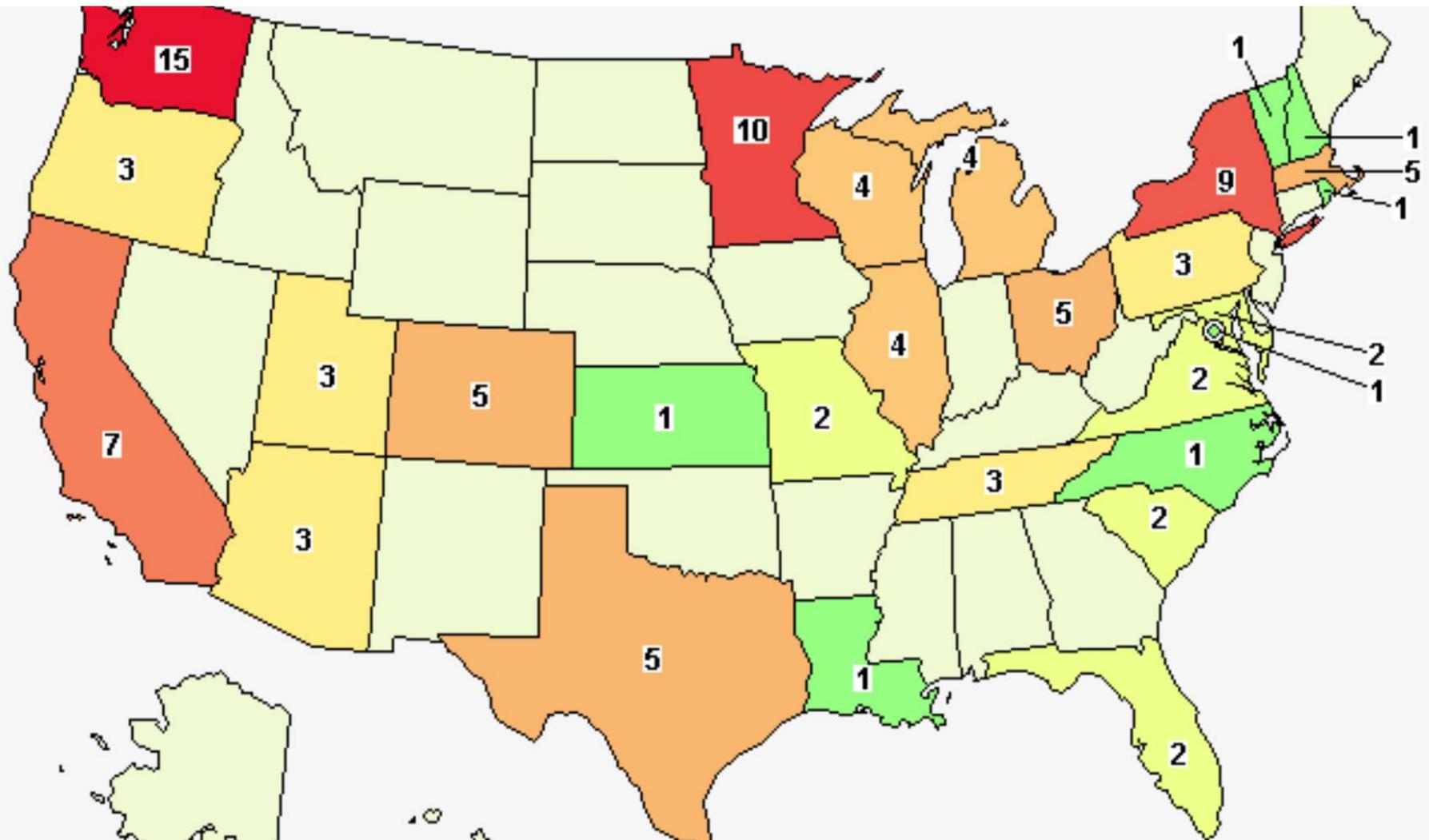
X

Distance ⓘ

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Search

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Row	Saved	Status	Study Title	Phase	NCT Number	Locations
1	<input type="checkbox"/>	Recruiting	A Study of Ulocuplumab And Ibrutinib in Symptomatic Patients With Mutated CXCR4 Waldenstrom's Macroglobulinemia	Phase 1 Phase 2	NCT03225716	<ul style="list-style-type: none"> Dana Farber Cancer Institute Boston, Massachusetts, United States
2	<input type="checkbox"/>	Recruiting	A Study of Daratumumab in Patients With Relapsed or Refractory Waldenström Macroglobulinemia	Phase 2	NCT03187262	<ul style="list-style-type: none"> Massachusetts General Hospital Boston, Massachusetts, United States Dana Farber Cancer Institute Boston, Massachusetts, United States
3	<input type="checkbox"/>	Not yet recruiting NEW	Ibrutinib and Ixazomib Citrate in Treating Participants With Relapsed or Refractory Waldenstrom Macroglobulinemia	Phase 2	NCT03506373	<ul style="list-style-type: none"> Mayo Clinic in Florida Jacksonville, Florida, United States
4	<input type="checkbox"/>	Recruiting	Immunotherapy for Asymptomatic Phase Lymphoplasmacytic Lymphoma	Phase 1	NCT01209871	<ul style="list-style-type: none"> University of Texas MD Anderson Cancer Center Houston, Texas, United States
5	<input type="checkbox"/>	Recruiting	Carfilzomib With or Without Rituximab in the Treatment of Waldenstrom Macroglobulinemia or Marginal Zone Lymphoma	Phase 2	NCT03269552	<ul style="list-style-type: none"> Fred Hutch/University of Washington Cancer Consortium Seattle, Washington, United States
6	<input type="checkbox"/>	Recruiting	Questionnaire and Tissue Banking For Multiple Myeloma, Waldenstrom Macroglobulinemia and Related Disorders		NCT01177527	<ul style="list-style-type: none"> Dana-Farber Cancer Institute Boston, Massachusetts, United States
7	<input type="checkbox"/>	Recruiting	Natural History Study of Monoclonal B Cell Lymphocytosis (MBL), Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Lymphoplasmacytic Lymphoma (LPL)/Waldenstrom Macroglobulinemia (WM), and Splenic Marginal Zone Lymphoma (SMZL)		NCT00923507	<ul style="list-style-type: none"> National Institutes of Health Clinical Center, 9000 Rockville Pike Bethesda, Maryland, United States
8	<input type="checkbox"/>	Recruiting	Study to Assess the Efficacy and Safety of Umbralisib in Patients With Non-Follicular Indolent Non-Hodgkin's Lymphoma	Phase 2	NCT03364231	<ul style="list-style-type: none"> TG Therapeutics Investigational



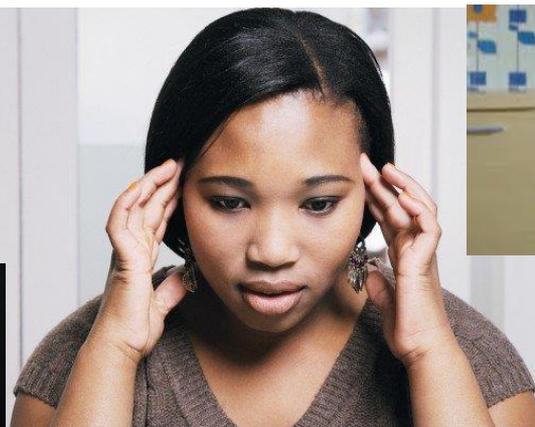
Finding Trials Can be Exasperating and Isolating



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bwc10379618 Barewalls ©



How Can The Leukemia & Lymphoma Society Help?



Multiple Organizations/Companies Are Attempting to Address These Challenges

- Governmental Databases
 - Clinicaltrials.gov-Largest database of clinical trials worldwide
 - Cancer.gov (National Cancer Institute) NCI supported clinical trials
- Clinical Trial Site Websites
 - MDAnderson.org
 - bloodcancerinstitute.com/clinical-trials/index.dot (CBCI trials)
- Patient Organizations
 - Cancer.org (American Cancer Society)
 - Cancer Support Community
 - Lazarex.org
- Industry Websites
 - researchoncology.com/clinical-trials/ (Celgene Clinical Trials)
- For Profit Companies
 - clinicalconnection.com/study-participant/become-a-member



LLS Commitment: To Providing Resources To Help Patients Access Clinical Trials

CTSC

- Highly trained nurses specialized in hematological malignancies
- Provide education to patient
- Provide patient with a professional, detailed, individualized search to discuss with their HCP
- Provide guidance and advocates throughout the clinical trial process
- Personal connection
- The CTSC nurses serve as a bridge between technology and patients





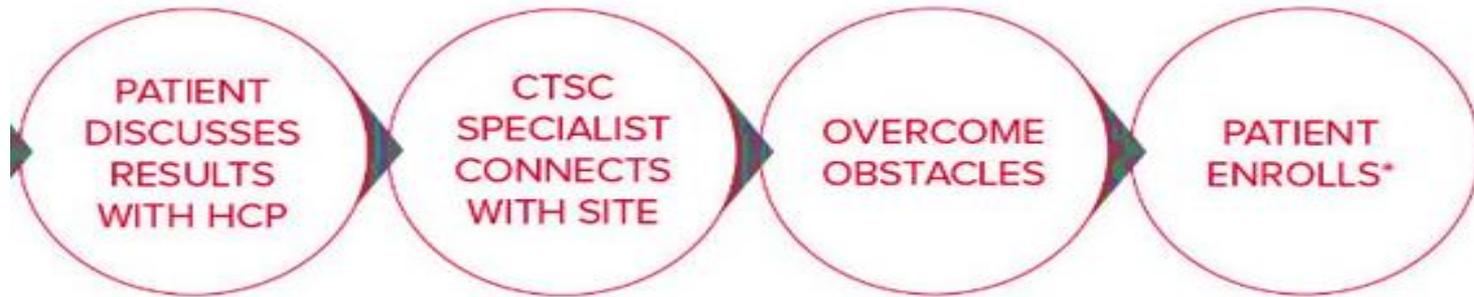
Clinical Trial Support Center (CTSC)



- ◆ Get to know the patient
 - ◆ Reasons seeking treatment under a trial; Barriers to enrollment (financial, support); General level of understanding of diagnosis, treatment, and clinical trials
- ◆ Support and education
 - ◆ Help patients understand the clinical trial process including rights and obligations as a participant
 - ◆ Clinical trial phases, criteria, demands, trade-offs
- ◆ Clinical intake
 - ◆ Prior treatments/response, current physical condition and past medical history that may impact eligibility for certain trials
- ◆ Conduct the search through clinicaltrials.gov
- ◆ Even with technology matching services, it takes time for nursing staff to find trials and help enroll patients into clinical trials



Clinical Trial Support Center (CTSC)



*The majority of eligible patients enter into clinical trials.

- Provide list of trials that patient can discuss with their healthcare team
 - Healthcare team often contacts site and proceeds with next steps in enrollment
- If the treatment team cannot contact site, CTSC will guide the patient in their efforts to enroll in a trial including connecting the patient with trial sites
- Help address obstacles to enrollment such as travel and lodging expense
- Give patients the tools needed to make informed decisions
- Be available for support throughout your experience in the trial

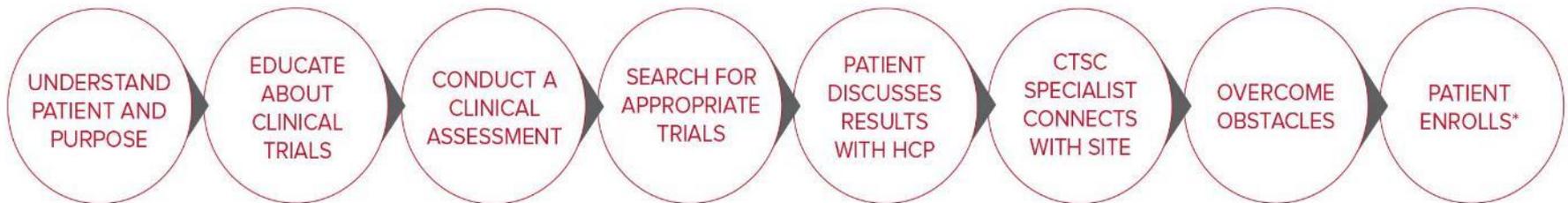


Clinical Trial Support Center (CTSC)



CLINICAL TRIAL SUPPORT CENTER (CTSC)

Process for Supporting Patients



*The majority of eligible patients enter into clinical trials.

To access the CTSC, call 1-800-955-4572

I Have Identified A Clinical Trial, Now What??



Process of Informed Consent

- Your doctor must give you an informed consent document before you enroll in a clinical trial
 - Must be in a language you understand
 - Ask for a language interpreter if needed
- Bring an advocate
- Ask your doctor to explain anything you don't understand



Rights of a Clinical Trial Participant

Any volunteer who gives his or her consent to participate in a clinical trial or who is asked to give his or her consent on behalf of another has the following rights:

1. To be told the purpose of the clinical trial
2. To be told all the risks, side effects or discomforts that might be reasonably expected
3. To be told of any benefits that can be reasonably expected
4. To be told what will happen in the study and whether any procedures, drugs or devices are different than those that are used as standard medical treatment.



Rights of a Clinical Trial Participant

5. To be told about options available and how they may be better or worse than being in a clinical trial.
6. To be allowed to ask any questions about the trial before giving consent and at any time during the course of the study.
7. To be allowed ample time, without pressure, to decide whether to consent or not to consent to participate.
8. To be told of any medical treatments available if complications occur during the trial.
9. To receive a signed and dated copy of the informed consent form.
10. To refuse to participate, for any reason, before and after the trials started.



What Do I Ask My Physician?

- What is being studied?
- Why do researchers believe the intervention being tested might be effective? Why might it not be effective? Has it been tested before?
- What are the possible interventions that I might receive during the trial?
- How will it be determined which interventions I receive (for example, by chance)?
- Who will know which intervention I receive during the trial? Will I know? Will members of the research team know?



What Do I Ask My Physician?

- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?
- What will I have to do?
- What tests and procedures are involved?
- How often will I have to visit the hospital or clinic?
- How long will the study last?
- Who will pay for my participation?



What Do I Ask My Physician?

- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this trial?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- Will results of the study be provided to me?
- Who will oversee my medical care while I am participating in the trial?
- What are my options if I am injured during the study?



Where to Learn More About Clinical Trials

Speak one-on-one with an Information Specialist who can assist you through cancer treatment, financial and social challenges and give accurate, up-to-date disease, treatment and support information, as well as information about the Clinical Trial Support Center.

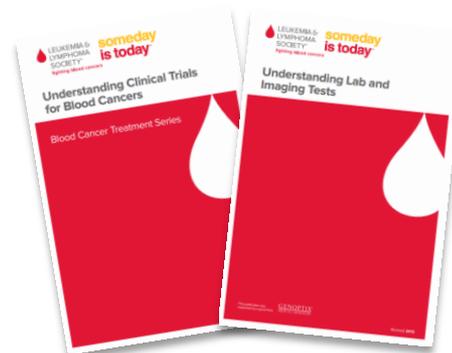
🔥 Contact an LLS Information Specialist for details about our Clinical Trial Support Center (CTSC)

🔥 **How to contact us**

🔥 **Call:** (800) 955-4572

Monday to Friday, 9 a.m. to 9 p.m. ET

🔥 **Email:** Infocenter@lls.org



CLINICAL TRIAL SUPPORT CENTER

Patients and caregivers can work one-on-one with The Leukemia & Lymphoma Society's (LLS) Clinical Trial Specialists who will personally assist them throughout the entire clinical-trial process, providing an additional resource to the healthcare team.

- LLS offers help for patients in understanding and identifying clinical trials and in connecting with clinical trial sites.
- Specialists are nurses specially trained in hematologic malignancies, clinical trials, and patient education/support.
- Patients will be provided with a list of appropriate clinical trials to discuss with their treating physician.
- Patients will have direct access to their LLS Clinical Trial Specialist for the duration of their search.

TO ACCESS THIS SERVICE:

Patients and caregivers can contact an LLS Information Specialist and state that they are seeking help with clinical trials:

- Call: **800.955.4572**
Monday to Friday, 9 am to 9 pm ET
- Chat live online:
LLS.org/informationsspecialists
Monday to Friday, 10 am to 7 pm ET
- Email: **infocenter@lls.org**



Check out these Free LLS Resources

- 🔴 Clinical Trial Support Center (CTSC) - www.LLS.org/ctsc
- 🔴 Publications - www.LLS.org/booklets
- 🔴 Podcasts - www.LLS.org/podcasts
- 🔴 Telephone/web education programs - www.LLS.org/programs
- 🔴 Videos - www.LLS.org/educationvideos
- 🔴 Information Specialists - www.LLS.org/information specialists
- 🔴 Family Support Groups - www.LLS.org/supportgroups
- 🔴 Moderated online chats - www.LLS.org/chat
- 🔴 Peer-to-peer support - www.LLS.org/firstconnection
- 🔴 Patient Community - www.LLS.org/community
- 🔴 Financial assistance - www.LLS.org/finances
- 🔴 Nutrition Consultation - www.LLS.org/nutrition
- 🔴 Your local LLS chapter www.LLS.org/chapterfind

**For information and to order materials, contact an
LLS Information Specialist at (800) 955-4572
or visit www.LLS.org**

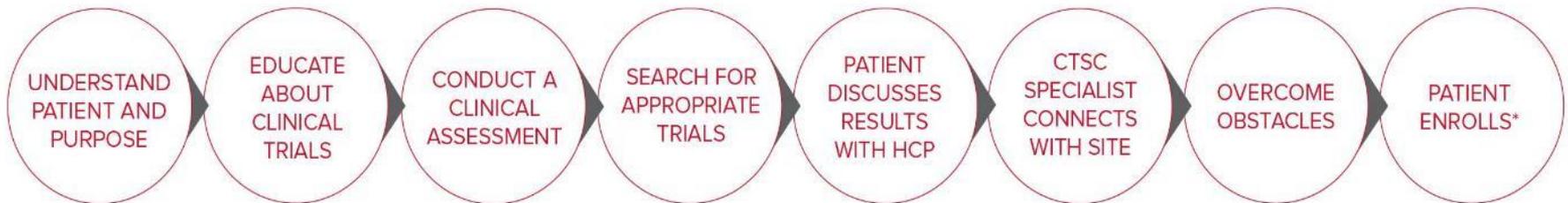


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Questions





References

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