

Clinical Trials: Understanding Opportunities And Advances In Treatment

North Texas Prostate Cancer Coalition
Annual Prostate Cancer Symposium May 24, 2025

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05/09/25 at 1520



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Objectives

Discuss common misconceptions about clinical trials

Understand how clinical trials are designed

Know who can participate in clinical trials

Assess the risks and benefits of clinical trials

Know how to find a clinical trial

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Common Misconceptions About Clinical Trials

Some patients perceive clinical trials as “experiments”

- In reality, clinical trials typically build on existing standards of care to improve outcomes or diminish adverse side effects
- Clinical trials are a component of high-quality care and patients who enroll in clinical trials are treated well.
- A survey about public attitudes and cancer clinical trials found that **90%** of individuals who participated in a clinical trial reported they were treated with dignity and respect and would recommend participation in clinical trials to others.

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Common Misconceptions About Clinical Trials

“Clinical trials are only for patients who have run out of other treatment options”

- Clinical trials are not only a “last resort” option.
- Clinical trials are frequently offered to patients as a first-line treatment.
- For patients who are not able or willing to participate in treatment trials, there are also trials related to symptoms management and quality of life. These trials are indispensable to advancing our knowledge about treatment effects.

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Common Misconceptions About Clinical Trials

"I may receive a placebo rather than treatment."

- Randomization is a common component of clinical trials but patients with active disease will never receive an option that is considered inferior to standard treatment.
- Typically, clinical trials compare standard treatment to a new agent.
- Sometimes both arms of the clinical trial will include the standard treatment, and the investigational arm will also include the investigational agent (in addition to, rather than in lieu of, standard treatment).

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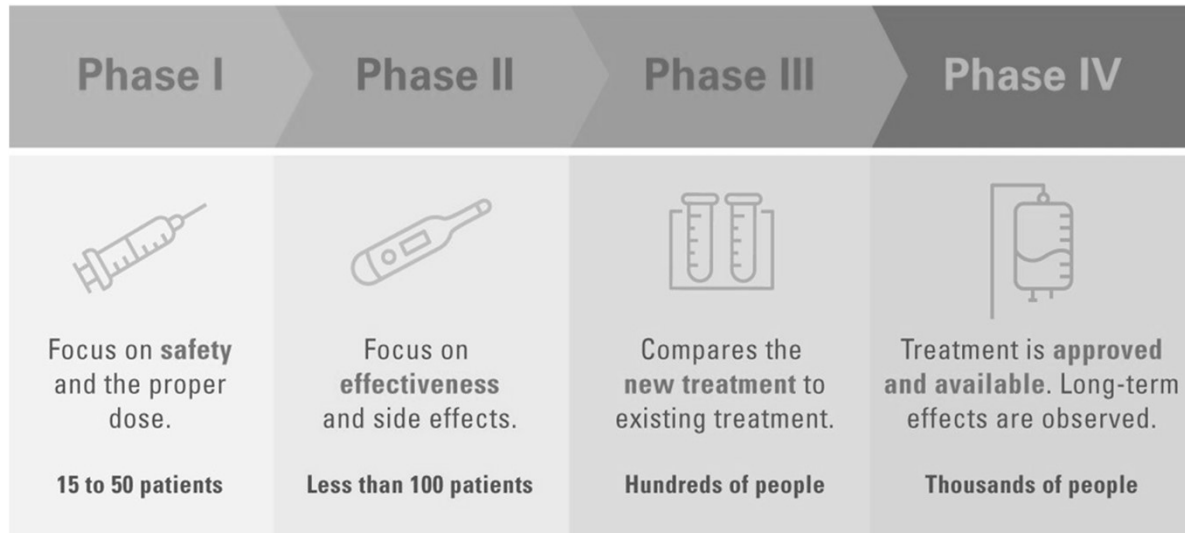
Clinical Trials Provide A High-quality Option For Care

Expert panels state that clinical trials provide a high-quality treatment option for cancer patients at all stages of the disease continuum

- **National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology:**
"...the best management of any cancer patient is in a clinical trial."
- **Institute of Medicine:** *"...therapies offered through Cancer Clinical Trials should ideally be considered the preferred treatment choice for physicians and patients, if they are available."*

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Phases Of Clinical Trials



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What are We Looking for? (Outcomes)

- . Non-inferiority to standard-of-care treatments with fewer harms
- . Delayed progression of disease
- . Disease-specific survival
- . Overall survival



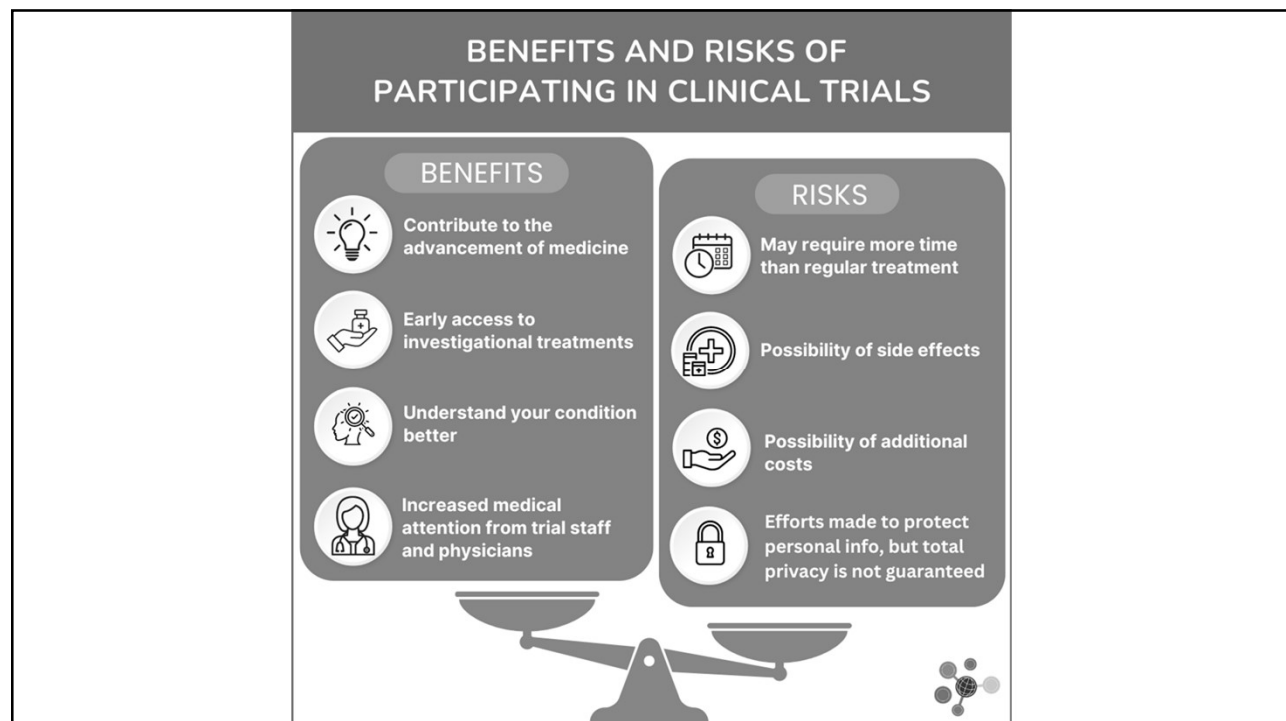
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Who Can Participate? (Prostate cancer)

- . Eligibility depends on:
 - . Stage of prostate cancer
 - . (localized, metastatic, etc.).
 - . Prior treatments received.
 - . Overall health and age.
- . Examples: Trials for newly diagnosed men, those with rising PSA after surgery, or metastatic castrate-resistant prostate cancer (mCRPC).
- . Consult with a doctor to find suitable trials.



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How is the Safety of Clinical Trial Patients Assured?

- Trial design is rigorously vetted by institutional review board (IRB)
- Potential harms are defined and strictly monitored (adverse events)



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Design Elements for a Clinical Trial

To determine the number of patients needed in each arm of a clinical trial comparing the standard of care (SOC) for prostate cancer (with an average overall survival of 60 months) versus SOC plus a new drug, with the goal of detecting at least a 12-month difference in overall survival at 95% confidence and 80% power, we need to perform a sample size calculation for a survival analysis.

You need approximately **661 patients per arm** (SOC and SOC + new drug), totaling 1,322 patients, to detect a 12-month difference in median overall survival (60 vs. 72 months) with 95% confidence ($\alpha=0.05$) and 80% power, assuming a 24-month accrual, 36-month follow-up, and 10% dropout rate. Use statistical software (e.g., R, PASS) to refine based on specific trial constraints.

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**If a Trial is Not
Demonstrating
a Benefit, or if
Patients are
Experiencing
More AE than
Expected:**

The trial may be
terminated early

Patients are free to stop
participating at any
time for any reason

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Current Treatments vs Clinical Trials

- Standard Treatments:
 - Surgery (prostatectomy)
 - Radiation therapy (external beam, brachytherapy, etc)
 - Hormone therapy: androgen deprivation (ADT)
 - Chemotherapy (Docetaxel)
- Clinical Trials:
 - Changes in surgical techniques
 - Test new drugs (e.g., PARP inhibitors, AR inhibitors)
 - Combination therapies (e.g. XRT + ADT + chemo)
 - Focus on personalized medicine (biomarkers and/or genetic testing)

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Example: Primary Radiation Therapy for Prostate Cancer

- Traditional Therapy:
 - IMRT / IGRT: 40 treatments over 8 weeks
- New Treatment Regimes:
 - Ultra hypofractionation: 7 treatments over 2.5 weeks
 - Result: Non-inferior (e.g. Hypo-RT-PC trial)
 - Use of adjuvant ADT (how long?) 6 months (e.g. NRG Oncology / RTOG 0815)
 - Result: Improved biochemical control and metastatic-free survival but did not improve overall survival

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What Happens When a Clinical Trial Shows a Benefit

- FDA approval for a specific indication
- Incorporation into treatment guidelines (e.g. NCCN, AUA)
- Acceptance by insurers
- New treatment approach, drug becomes part of the new standard-of-care



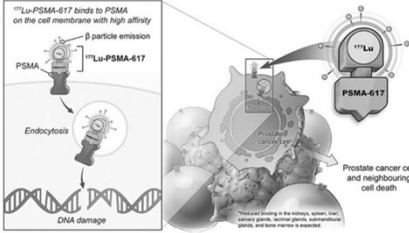
Guidelines

The AUA's Clinical Practice Guidelines provide evidence-based guidance with an explicit clinical scope and purpose. AUA Guidelines are an important resource for members and provide urology professionals with the best in peer-reviewed treatment recommendations and research updates. [Learn More >](#)

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Breaking News: Expanded FDA Approval of ¹⁷⁷Lutetium-PSMA-617

Approval means more treatment options for patients with metastatic castration-resistant prostate cancer



What this means for patients: Today, the therapy ¹⁷⁷lutetium-PSMA-617 (Lu-PSMA; trade name Pluvicto®) was approved by the FDA for patients with advanced (metastatic) prostate cancer who have been treated with androgen receptor pathway inhibitor therapy. This medicine delivers a small dose of radiation attached to a molecule that specifically binds to prostate cancer cells. It has been shown to slow disease progression and maintain quality of life in patients with advanced prostate cancer.

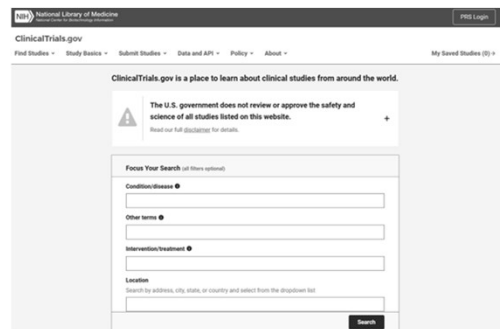
If you have advanced prostate cancer, speak with your doctor about treatment options and additional tests that might help guide your treatment.

Dr. Oliver Sartor, Director of Radiopharmaceutical Clinical Trials at Mayo Clinic Comprehensive Cancer Center, speaks with Dr. Zachary Klaassen of the Georgia Cancer

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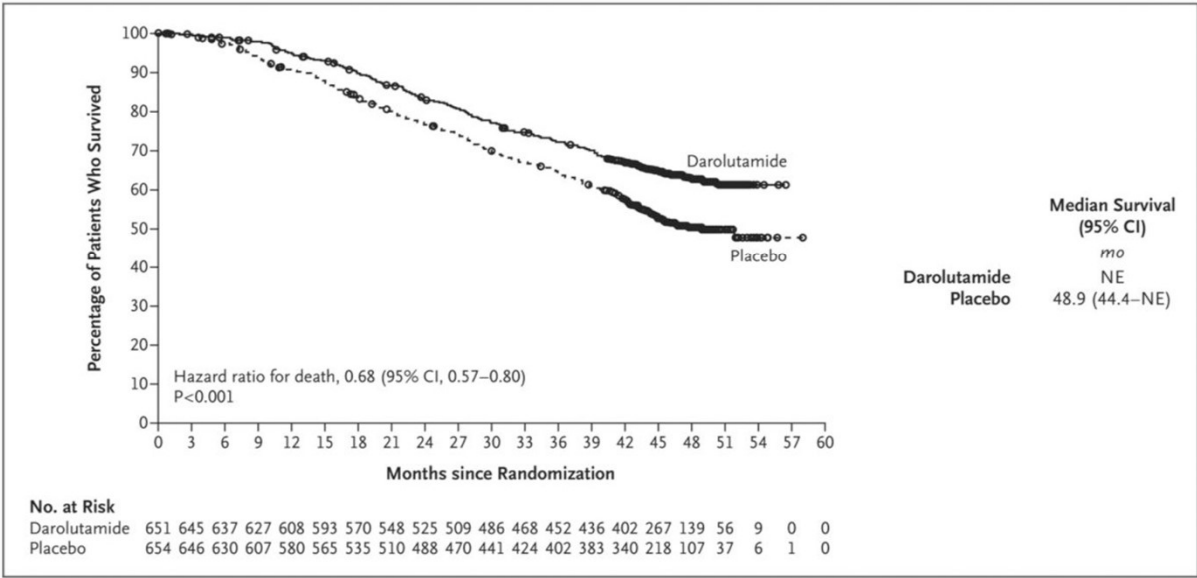
How To Learn Which Clinical Trial May Be Appropriate For You

- Talk with your urologist, medical oncologist or other healthcare provider about the options for participating in a clinical trial.
- Visit clinicaltrials.gov and search for trials near your location related to your condition.



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Aranote Trial



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Current Trials

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Current UCNT Prostate Cancer Trials

- Newly diagnosed:
 - RALP/PLND planned, high-risk or very high-risk PCA
 - Metastatic at the time of diagnosis
- Biochemical recurrence
- Recurrent - metastatic
- Metastatic castrate-resistant

These are “inflection points” – changes in the disease state

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The screenshot displays the UrologyClinics.com website. The header includes the site name and navigation links. A sidebar on the right lists 'Currently Enrolling Studies', 'Volunteer Info', 'Sponsor/CRO Info', 'Facilities', and 'Frequently Asked Questions (FAQ)'. The main content area is titled 'Enrolling Clinical Research Studies' and lists several trials:

- AURA Non-Muscle Invasive Bladder Cancer**: Apply for future studies
- Astellas PRL-02-1001**: CONFIDENCE Prostate Cancer Decision Impact Trial
- CORE-008**: Clarify CLP04 High-risk Prostate Cancer
- Debio 4228-201**: Advanced/Metastatic Prostate Cancer
- EvoPAR**: Expanded Access Program for the Identification of Clear Cell Renal
- MK-5684-004**: Metastatic Castrate Resistant Prostate Cancer
- MK3475-676**: Non-Muscle Invasive Bladder Cancer - CIS
- MoonRISe-1**: Intermediate-Risk Non-muscle Invasive Bladder Cancer
- ORIC Metastatic Prostate Cancer**: PSMA Care: Castration-Resistant Prostate Cancer (CRPC)
- Promise Registry/Prostate Cancer**: STREAM Optilume Post Market Study
- SunRISe-5**: High-risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)

On the right side of the main content, there is a section for **Texas Health Presbyterian Hospital of Dallas**, formerly known as Presbyterian Hospital of Dallas. Below this, the **Urology Clinics of North Texas Clinical Trials Office** is listed with the address: 8230 Walnut Hill Lane, Professional Building 3, Suite 700, Dallas, Texas 75231. Contact information includes phone numbers 214-580-1482 and 214-691-9374.

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Current Clinical Trial: Omaha-004 (MK-5684-004)

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation. For example, you must be at least 18 years old and have:

- Advanced mCRPC (stage 4 metastatic prostate cancer)
- mCRPC that became worse within 6 months before starting the trial and:
 - o After being treated with drugs or surgery to block your testes from making hormones

AND

- o After treatment with other drugs for prostate cancer

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

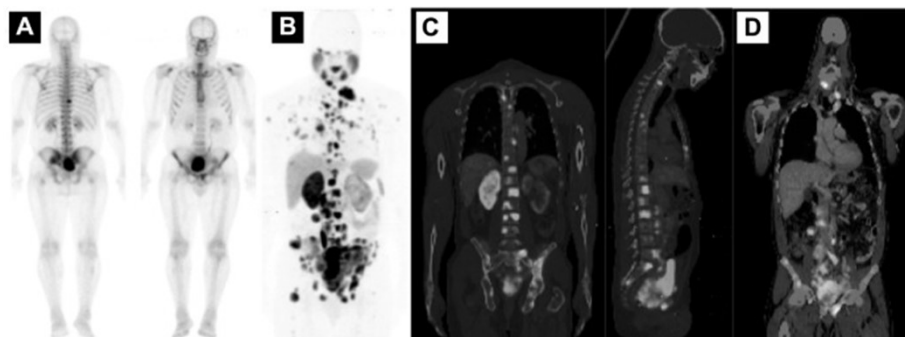
- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

<https://clinicaltrials.gov/study/NCT06136650?term=Prostate%20Cancer&titles=MK-5684&rank=8#participation-criteria>

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CURRENT TRIAL: (clarify) PSMA-PET CT in Participants With High-risk Prostate Cancer Prior to Radical Prostatectomy

- CU-64 Imaging agent has two sites for PSMA binding
- Possible increased sensitivity for metastatic disease
- Scans to be done prior to surgery with comparison to surgical pathology to evaluate accuracy



<https://clinicaltrials.gov/study/NCT06056830?cond=prostate%20cancer&titles=clarify&rank=1>

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Grok.com Search

SuperGrok

Are there any current trials for prostate cancer when PSA is rising while on ADT and NHA

25 web pages

Provides an overview. The list is not complete.

Grok ultimately recommended checking clinicaltrials.gov

Your question focuses on clinical trials for prostate cancer patients experiencing a rising PSA while on androgen deprivation therapy (ADT) and next-generation hormonal agents (NHAs), such as enzalutamide (Xtandi), abiraterone (Zytiga), apalutamide (Erleada), or darolutamide (Nubeqa). This scenario typically indicates progression toward castration-resistant prostate cancer (CRPC), where the cancer grows despite testosterone suppression and androgen receptor blockade. As of April 7, 2025, I'll outline relevant ongoing or recently active trials based on current trends and available data, though exact statuses may require real-time verification via ClinicalTrials.gov or similar registries.

Relevant Context

Rising PSA on ADT + NHA often signals treatment resistance, prompting trials to explore next-line therapies, combination strategies, or novel agents. Current research emphasizes metastatic CRPC (mCRPC), but some trials include non-metastatic CRPC (nmCRPC) or hormone-sensitive settings with progression. Common approaches include:

- Adding chemotherapy (e.g., docetaxel, cabazitaxel).
- Targeting alternative pathways (e.g., PARP inhibitors, PSMA-directed therapies).
- Combining immunotherapies or radiopharmaceuticals.

Current or Recent Trials

Here are trials that align with your query, focusing on PSA progression while on ADT + NHA:

1. NCT04495179 (Phase 2) - Xtandi + Carboplatin

How can Grok help?

DeepSearch Think

Grok 3

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Right To Try: Senate Bill 204 (2017)

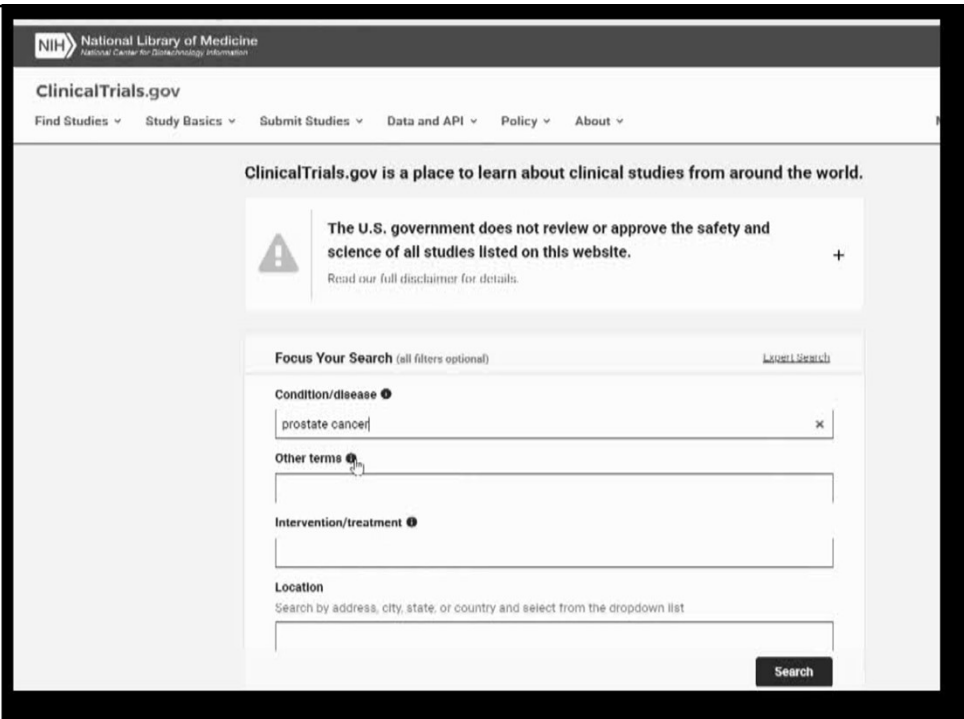
Who Qualifies for Right to Try?

To be eligible for Right to Try, a patient must meet the following conditions:

- Be diagnosed with a life-threatening disease or condition;
- Have exhausted approved treatment options;
- Be unable to participate in a clinical trial involving the eligible investigational drug, as certified by a doctor, who is in good standing with her licensing organization and will not be compensated directly by the manufacturer for so certifying; and
- Give written informed consent regarding the risks associated with taking the investigational treatment.

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Video



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