# Open Clinical Trials for Patients With Cancer

A significant number of trials are now recruiting patients from veteran and active-duty military patient populations. Many trials explicitly recruit patients from the US Department of Veterans Affairs (VA) and Defense (DoD), as well as the Indian Health Service (IHS). The VA Office of Research and Development alone funded > 7260 research projects in 2022, and many more are sponsored by Walter Reed National Military Medical Center and other federal facilities. The clinical trials listed below are all open as of April 1, 2023; have at least 1 federal location recruiting patients; and are focused on treatments for prostate and lung cancer. For additional information and full inclusion/exclusion criteria, please consult clinicaltrials.gov.

## PROSTATE CANCER

### 18F-DCFPyL PET/CT Impact on Treatment Strategies for Patients With Prostate Cancer (PROSPYL)

The main purpose of this phase II trial study is to determine whether a positron emission tomography (PET)/computed tomography (CT) scan using 18F-DCFPyL affects the clinical management plan in veterans. In this study, the management plan prior to and after 18F-DCFPyL PET/CT will be recorded by specific questionnaires and corresponding changes in management will be analyzed. The scan will be used to see how the disease has spread. Both the treatment strategies and probable disease outcomes as relevant to clinical endpoints will be assessed. This study is open to veterans only.

**ID:** NCT04390880
**Sponsor:** VA Greater Los Angeles Healthcare System
**Location:** VA Greater Los Angeles Healthcare System

### Patient Decision-Making About Precision Oncology in Veterans With Advanced Prostate Cancer

This project proposes to understand and improve veterans' decision-making in precision oncology (germline testing, somatic tumor testing, and targeted therapy) for advanced prostate cancer. As precision oncology expands, a comprehensive strategy to support patient informed decision-making has not been developed.

**ID:** NCT05396872
**Sponsor; Collaborator:** University of California, San Francisco; US Department of Defense
**Location:** San Francisco VA Medical Center

### Intramuscular Mechanisms of Androgen Deprivation-Related Sarcopenia

Prostate cancer is the most common cancer among men and is even more common in the military and veteran population. For patients with advanced prostate cancer, the most common treatment includes lowering the levels of the hormone testosterone as much as possible, which is called androgen deprivation therapy (ADT). Unfortunately, ADT also causes patients to be fatigued, weak, and to lose muscle. This is often referred to as sarcopenia, and it leads to falls, poor quality of life, and higher risk of death. Currently, there is no treatment for sarcopenia because investigators do not understand the mechanisms that cause it. The mitochondria is the part of the cells responsible for providing energy to muscles but to date the investigators do not know if it is affected in prostate cancer patients with sarcopenia due to ADT. The overall goal of this proposal is to establish if the mitochondria is responsible for sarcopenia in patients with prostate cancer receiving ADT. The investigators will measure mitochondrial function, muscle mass and strength, and feelings of fatigue and quality of life in patients with prostate cancer before starting and after 6 months of ADT.

**ID:** NCT03867357
**Sponsor; Collaborator:** Seattle Institute for Biomedical and Clinical Research; US Department of Defense
**Location:** VA Puget Sound Health Care System

### VA Seamless Phase II/III Randomized Trial of Standard Systemic Therapy With or Without PET-Directed Local Therapy for OligoRecurrent Prostate Cancer (VA STARPORT)

The primary goal of this study is to determine if adding PET-directed local therapy improves disease control compared to standard systemic therapy alone (SST) in veterans with oligorecurrent prostate cancer on PET/CT. The investigators will conduct a multi-institutional phase II/III randomized trial comparing SST with or without PET-directed local therapy using radiation or surgery to all metastases and if a local recurrence is present.

**ID:** NCT04787744
**Sponsor:** VA Office of Research and Development
**Locations:** VA Long Beach Healthcare System, VA Greater Los Angeles Healthcare System, Bay Pines VA Healthcare System, Edward Hines Jr. VA Hospital, Richard L. Roudebush VA Medical Center, VA Boston Healthcare System Jamaica Plain Campus, VA Ann Arbor Healthcare System, Minneapolis VA Health Care System, Kansas City VA Medical Center, St. Louis VA Medical Center John Cochran

Division, East Orange Campus of the VA New Jersey Health Care System, Durham VA Medical Center, Louis Stokes VA Medical Center, Michael E. DeBakey VA Medical Center, Hunter Holmes McGuire VA Medical Center, Clement J. Zablocki VA Medical Center

### Standard Systemic Therapy With or Without Definitive Treatment in Treating Participants With Metastatic Prostate Cancer

This phase III trial studies how well standard systemic therapy with or without definitive treatment (prostate removal surgery or radiation therapy) works in treating participants with prostate cancer that has spread to other places in the body. The addition of prostate removal surgery or radiation therapy to standard systemic therapy for prostate cancer may lower the chance of the cancer growing or spreading.

**ID:** NCT03678025

**Sponsor; Collaborator:** Southwest Oncology Group; National Cancer Institute (NCI)

**Locations:** 328 sites, including Tibor Rubin VA Medical Center, Atlanta VA Medical Center, James J. Peters VA Medical Center, Michael E. DeBakey VA Medical Center, and Audie L. Murphy VA Hospital

### A Clinical Study Evaluating the Benefit of Adding Rucaparib to Enzalutamide for Men With Metastatic Prostate Cancer That Has Become Resistant to Testosterone-Deprivation Therapy (CASPAR)

This randomized, placebo-controlled, phase III trial is evaluating the benefit of rucaparib and enzalutamide combination therapy vs enzalutamide alone for the treatment of men with prostate cancer that has spread to other places in the body (metastatic) and has become resistant to testosterone-deprivation therapy (castration-resistant). Enzalutamide helps fight prostate cancer by blocking the use of testosterone by the tumor cells for growth. Poly adenosine diphosphate (ADP)-ribose polymerase (PARP) inhibitors, such as rucaparib, fight prostate cancer by prevent tumor cells from repairing their DNA. Giving enzalutamide and rucaparib may make patients live longer or prevent their cancer from growing or spreading for a longer time, or both. It may also help doctors learn if a mutation in any of the homologous recombination DNA repair genes is helpful to decide which treatment is best for the patient.

**ID:** NCT04455750

**Sponsor; Collaborator:** Alliance for Clinical Trials in Oncology; National Cancer Institute (NCI)

**Locations:** 413 sites

### Digitally Captured Activity Data and PROs to Monitor Physical Function in Prostate Cancer Patients (DigiPRO)

Physical function is a known predictor of quality of life in advanced prostate cancer patients and key measure of treatment tolerability. While treatment with androgen deprivation therapy (ADT) improves survival, it is associated with significant toxicities that lead to physical function (PF) decline. The average age of incident prostate cancer is 66 years, and in this older group of men, chronic comorbid conditions often co-occur with diagnosis, further adding to the risk for PF decline. With over 2.9 million prostate cancer survivors in the US, there is an increasing demand for adequate symptom monitoring and PF assessment throughout cancer care. However, there are currently no validated methods to systematically evaluate and predict PF decline. Thus, the overarching objective of this proposal is to determine whether the use of wearable technology to monitor objective daily activity combined with routine symptom reporting can predict PF decline. To accomplish this, we propose a mixed-methods approach that will provide quantitative information to help identify PC survivors at higher risk for PF decline as well as a qualitative aim gain a deeper understanding of the perceived relationships that PC survivors have with their physical activity levels and treatment symptoms.

**ID:** NCT04575402

**Sponsor; Collaborator:** Cedars-Sinai Medical Center; US Department of Defense

**Location:** Cedars Sinai Medical Center

### The BurnAlong Pilot Study for Adolescent and Young Adult Cancer Survivors

The purpose of this prospective, interventional, single-arm pilot study is to evaluate whether virtually delivered group-based physical activity is feasible for adolescent and young adult (AYA) cancer survivors. AYAs who were diagnosed with cancer and have completed cancer treatment will be recruited for this study. This study will enroll 20 participants in total and will last approximately 3 months.

**ID:** NCT05131815

**Sponsor; Collaborator:** Cedars-Sinai Medical Center; Walter Reed National Military Medical Center

**Location:** Cedars-Sinai Medical Center

## LUNG CANCER

### DECAMP 1 PLUS: Prediction of Lung Cancer Using Noninvasive Biomarkers

The Detection of Early lung Cancer Among Military Personnel (DECAMP) consortium is a multidisciplinary and translational research program for lung cancer early detection. DECAMP 1 PLUS aims to improve the efficiency of the diagnostic

evaluation of patients with indeterminate pulmonary nodules (8-25 mm). Molecular biomarkers for lung cancer diagnosis measured in minimally invasive and noninvasive biospecimens may be able to distinguish between malignant or benign indeterminate pulmonary nodules in high-risk smokers. Ultimately, this study aims to validate molecular as well as clinical and imaging biomarkers of lung cancer in individuals with indeterminate lung nodules.

**ID:** NCT04165564

**Sponsor:** Boston University

**Locations:** 3 VA medical centers (VA Greater LA Healthcare System, VA Boston Healthcare System, and VA Tennessee Valley Healthcare System), 3 military treatment facilities (Naval Medical Center San Diego, Walter Reed National Military Medical Center, and Naval Medical Center Portsmouth) and 12 academic hospitals

## DECAMP-2: Screening of Patients With Early Stage Lung Cancer or at High Risk for Developing Lung Cancer (DECAMP-2)

The goal of this project is to improve lung cancer screening in high-risk individuals by identifying biomarkers of preclinical disease and disease risk that are measured in minimally invasive and noninvasive biospecimens. Existing biomarkers for lung cancer diagnosis as well as new biomarkers discovered specifically in this clinical setting will be examined. Biomarkers that identify individuals at highest risk for being diagnosed with lung cancer prior to the appearance of concerning symptoms could increase the utility of lung cancer surveillance and the efficiency of lung cancer chemoprevention clinical trials. Achieving these goals would improve the detection and treatment of early-stage and incipient lung cancer, while restricting the risk of these procedures to those individuals who currently exhibit the early molecular warning signs of impending disease.

**ID:** NCT02504697

**Sponsor:** Boston University

**Locations:** VA medical centers (including Los Angeles VA Healthcare System, Boston VA Research Institute, Inc, Philadelphia VA Medical Center, Veterans Research Foundation of Pittsburgh, and VA North Texas Health Care System), 4 military treatment facilities (Naval Medical Center San Diego, Walter Reed National Military Medical Center, San Antonio Military Medical Center, and Naval Medical Center Portsmouth), and 4 academic hospitals

## Improving Decision-Making Encounters in Lung Cancer Using a Low-Literacy Conversation Tool (iDECIDE)

This clinical trial evaluates the effectiveness of a conversation tool on patient-centered health and decision-making outcomes in patients with lung cancer making treatment decisions. This research is being conducted to help doctors understand the information patients need to participate in shared decision-making about their lung cancer treatment options. The focus of this research is to study how patients choose lung cancer treatment options and the information needed to make that choice, with a focus on patients with lower health literacy.

**ID:** NCT05407168

**Sponsor:** Oregon Health & Science University Knight Cancer Institute

**Locations:** Portland VA Medical Center and Oregon Health & Science University Knight Cancer Institute

## VA Lung Cancer Surgery or Stereotactic Radiotherapy (VALOR)

The standard of care for stage I non–small cell lung cancer has historically been surgical resection in patients who are medically fit to tolerate an operation. Recent data now suggest that stereotactic radiotherapy may be a suitable alternative. This includes the results from a pooled analysis of 2 incomplete phase III studies that reported a 15% overall survival advantage with stereotactic radiotherapy at 3 years. While these data are promising, the median follow-up period was short, the results underpowered, and the findings were in contradiction to multiple retrospective studies that demonstrate the outcomes with surgery are likely equal or superior. Therefore, the herein trial aims to evaluate these 2 treatments in a prospective randomized fashion with a goal to compare the overall survival beyond 5 years. It has been designed to enroll patients who have a long life expectancy and are fit enough to tolerate an anatomic pulmonary resection with intraoperative lymph node sampling.

This study is designed to open at VA medical centers with expertise in both treatments. The recruitment process includes shared decision making and multidisciplinary evaluations with lung cancer specialists. Mandatory evaluations before randomization include tissue confirmation of NSCLC, staging with FDG-PET/CT, and biopsies of all hilar and/or mediastinal lymph nodes > 10 mm that have a SUV > 2.5. Prerandomization elective lymph node sampling is strongly encouraged, but not required. Following treatment, patients will be followed for a minimum of 5 years.

**ID:** NCT02984761

**Sponsor:** VA Office of Research and Development

**Locations:** 17 VA medical centers, including VA Long Beach Healthcare System, VA Greater Los Angeles Healthcare System, Bay Pines VA Healthcare System, Miami VA Healthcare System, Edward Hines Jr. VA Hospital, Richard L. Roudebush VA Medical Center, Baltimore VA Medical Center, VA Boston Healthcare System Jamaica Plain Campus, VA Ann Arbor Healthcare System, Minneapolis VA Health Care System, Durham VA Medical Center, Louis Stokes VA Medical Center,

Corporal Micheal J. Crescenz VA Medical Center, VA Pittsburgh Healthcare System University Drive Division, Michael E. DeBakey VA Medical Center, Hunter Holmes McGuire VA Medical Center, and Clement J. Zablocki VA Medical Center

## Utility of CAML as Diagnostic for Early Stage Lung Cancer

The primary objective of this study is to determine the prevalence of cancer associated macrophage-like cells (CAMLS) in patients with pulmonary nodules. Secondary objectives include the following: determine the positive and negative predictive value of CAMLS in patients with pulmonary nodules who undergo biopsy; model combinations of clinical factors with the presence/absence of CAMLS to refine strategies for assessment of patients with pulmonary nodules; and evaluate whether these measures result in enhanced T-cell activity and/or natural killer cell function and number.

**ID:** NCT03992183

**Sponsor; Collaborators:** Fox Chase Cancer Center; US Department of Defense

**Locations:** Corporal Michael J. Crescenz VA Medical Center and Fox Chase Cancer Center

## PROSPECT - Profiling of Resistance Patterns & Oncogenic Signaling Pathways in Evaluation of Cancers of the Thorax and Therapeutic Target Identification

This study will use therapeutic target-focused (TTF) profiling, genome-wide mRNA profiling, and assessments of tumor phosphopeptides and DNA that are shed into the bloodstream to define how various molecular factors alone and in combination relate to resistance to therapy, to prognosis, and to metastatic patterns at relapse. This study will examine how the presence of factors that drive cell growth, antagonize apoptosis, or confer resistance in other ways may counter the effect of systemic therapies and/or promote rapid tumor recurrence. In this way, the investigators will identify new, previously unappreciated potential therapeutic targets while also identifying which targets are most likely to increase resistance to therapy and worsen prognosis.

**ID:** NCT05049837

**Sponsor; Collaborators:** MD Anderson Cancer Center; US Department of Defense, National Institutes of Health (NIH), and National Cancer Institute (NCI)

**Location:** MD Anderson Cancer Center

## Tribally Engaged Approaches to Lung Screening (TEALS)

Lung cancer is the leading cause of cancer mortality among American Indians and Alaska Natives (AI/AN), and AI/AN have worse lung cancer incidence rates, survival, and death compared to the general population. Because lung cancer screening (LCS) with low-dose computed tomography (LDCT) has been shown to reduce lung cancer mortality by roughly 20%, the US Preventive Services Task Force now recommends LCS for persons aged 55 to 80 years who meet specific eligibility criteria (grade-B evidence), and subsequently the Center for Medicare and Medicaid Services (CMS) opted to cover this test. However, the uptake of LCS implementation has been slow in most health care systems, and LCS implementation among AI/AN has never been studied.

To address this knowledge, the Tribally Engaged Approaches to Lung Screening (TEALS) study, a collaborative effort between the Choctaw Nation of Oklahoma, the Stephenson Cancer Center, and the University of Oklahoma Health Sciences Center, will address the following over the course of 5 years: conduct focus groups and semistructured interviews with Choctaw Nation Health Services Authority (CNHSA) patients, clinicians, and health administrators to elucidate individual- and system-level barriers and facilitators that affect the implementation of LCS; develop an LCS care coordination intervention that will identify eligible persons for LCS, help these patients navigate the screening process, and link them with smoking cessation services, when applicable; measure the impact of the TEALS intervention on the receipt of screening and a set of patient- and practice-level outcomes by conducting a cluster-randomized clinical trial of LCS implementation; and disseminate the TEALS program to other researchers and healthcare systems that serve AI/AN patients. TEALS will bridge the gap between evidence and clinical practice for LCS in a high-need, low-resource setting by intervening at the level of the healthcare system.

System-level interventions for guideline implementation tend to be understudied compared to those evaluating individual-level, behavioral interventions. However, the careful development and evaluation of an LCS screening program at the level of the healthcare system would be critical to ensure that more patients can receive LCS. Our research will create a critically needed platform from which future studies could be launched that will examine how to tailor the application of the LCS guideline to the individual preferences of AI/AN patients. TEALS will establish an effective LCS program in a tribal system and thus provide a direct benefit to the Choctaw Nation by increasing LCS participation. TEALS will serve as a blueprint for establishing a sustainable and accessible infrastructure for LCS in AI/AN and other community health systems. By increasing screening for early stage lung cancer, TEALS could ultimately reduce lung cancer mortality in AI/AN communities.

**ID:** NCT04948060

**Sponsor; Collaborator:** University of Oklahoma; Choctaw Nation of Oklahoma

**Location:** University of Oklahoma Health Sciences Center