

The VCS Research Institute



Clinical Trials in Your Community



Virginia Cancer
Specialists

RESEARCH INSTITUTE

A Welcome to Our Program

We at the VCS Research Institute are pleased to provide this reference to you as a guide to clinical trials and the proud accomplishments of our program, the only such program in the Northern Virginia area for patients with cancer. Founded by Dr. Nicholas Robert over 16 years ago, the VCS clinical trials and research program has expanded to more than 30-40 active trials for almost all types of cancer. An integral part of Virginia Cancer Specialists, one of the region's top-notch hematology and oncology practices, the VCS Research Institute serves to provide the best clinical care to all of our patients, close to home.

Our trials focus on providing participants with the opportunity to receive new drug combinations or completely novel therapies while still receiving state of the art care. Through our offerings, our patients have had access to numerous targeted therapies, such as second and third generation EGFR inhibitors, second generation ALK-inhibitors, vaccine therapy, PARP inhibitors, and immunotherapy. Many of the patients enrolled in these trials received drugs that ultimately received FDA approval, and all contributed to the scientific and medical knowledge of oncology.

Our research team involves dedicated members of our entire practice. Our knowledgeable physicians have had over 50 research papers published in top-notch journals in the past few years. Furthermore, they dedicate themselves to finding answers for participants and the field of oncology. If an individual decides to participate, he or she will also be assigned to a highly trained clinical research coordinator (CRC) to answer questions and walk him or her through the process step-by-step.

This brochure is only the beginning. We encourage you to read through this information and ask questions. Any member of our research program would be happy to assist. Thank you.

Alex I. Spira, MD, PhD, FACP
Director, VCS Research Institute

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Co-Director, VCS Research Institute

How Do Clinical Trials Work?



What are Clinical Trials?

Clinical trials are research studies conducted with people who volunteer to participate in the testing of new therapies. The purpose of these studies is to find better therapies for cancer treatment. Clinical research trials are designed by physicians and researchers who develop an action plan (protocol) that describes what will be done in the study, how it will be conducted and why each part of the study is necessary. Each study has eligibility criteria for who can or cannot participate in the study, which may include type of cancer, age, gender, medical history and current health status. This protocol is used by every doctor taking part in the study.

How Can Patients Participate in Trials?

In order to participate in an open trial, a patient must be given the opportunity to read and review a consent form that is specific for the trial. Following careful review and discussion with one's Physician or the physician running the trial at VCS, the patient will meet with a Clinical Research Coordinator (CRC) who will be the main contact during the course of the study. There may be specific tests for the study, such as an echocardiogram, EKG, blood work, or even a biopsy of the patient's cancer. Following this, if all criteria are met, the patient will then start treatment "on study".

To get started, you can find open trials on our website at VirginiaCancerSpecialists.com/treatments-services/clinical-trials-reasearch or through such resources as clinicaltrials.gov.

Benefits of Participating in Trials

There are many benefits to participating in clinical trials although they are not mandatory and the choice to participate is always the patient's. Patients who participate in clinical trials have access to treatments not yet available to others not involved in the specific study. During and after the trial, patients will receive top-notch, closely-monitored medical care. Trial participation also enables patients to take an active role in their medical care while leading to possible new discoveries in medicine that can ultimately help others.

Types of Trials

There are four phases of clinical trials. At the VCS Research Institute, we offer trials in all four phases, including Phase I trials, which study drugs at their earliest stage of development. The Phases are as follows:

PHASE I

Phase I trials test a drug for the first time in a group of 20 to 80 people to evaluate proper dosing and safety.

PHASE II

Drugs in Phase II trials are tested in groups of 100 to 300 people to test effectiveness and safety.

PHASE III

Phase III trials use groups of 1,000 to 3,000 people to compare the drug to approved treatments and further evaluate effectiveness in preparation to safely market the drug.

PHASE IV

Phase IV trials test drugs after they have been marketed to monitor long-term side effects.

The VCS Research Institute Program



A Commitment to Quality

The VCS Research Institute Program has a long-standing commitment to quality and to advancing medicine. Started by Nicholas Robert, MD in 1998, the program began with a focus on cooperative group studies. Since that time, over 1000 patients have participated in trials at VCS. This has led to the approval of many drugs and helped patients actively participate in their care. At the VCS Research Institute, we believe that through clinical trials and research, we can discover novel, targeted therapies that can change the face of cancer care. Our physician experts are actively involved in the clinical trial process, monitoring each tumor entity and participating in meetings and committees for the development of the study drugs. To ensure patient care and safety are optimized, the leadership and staff of the VCS Research Institute hold weekly oversight meetings to review all patients actively participating on study. All studies are also reviewed by the Institutional Review Board (IRB) to ensure safety.



Community-Based Care with National Support

The VCS Research Institute offers access to the latest clinical trials for patients right in their community. As a part of Virginia Cancer Specialists (VCS), a 27-physician practice with locations throughout Northern Virginia, the VCS Research Institute is committed to an integrated, community-based philosophy towards cancer care. When patients participate in clinical trials with the VCS Research Institute, they have access to the other services that VCS has to offer as well.

Virginia Cancer Specialists and the VCS Research Institute are also members of US Oncology, a network of over 1,000 community-based oncologists throughout the nation. As members of US Oncology, VCS and the VCS Research Institute have access to resources and support not available to many practices. The VCS Research Institute also participates with US Oncology Research, the clinical trials and research-focused arm of US Oncology, which has helped contribute to the development of 50 FDA-approved drugs.



Phase I Clinical Trials through the Translational Oncology Program (TOP)

Through US Oncology Research, the VCS Research Institute has the benefit of membership in the Translational Oncology Program (TOP), a program designed to consider the extra safety measures needed for Phase I trials. As a part of TOP, the VCS Research Institute has additional support in conducting ground-breaking, Phase I research. This allows the Institute to bring new, innovative trials to patients, including first-in-human trials. The VCS Research Institute is one of only 14 sites in the U.S. to be a member of the Translational Oncology Program.

Novel and Personalized Approaches to Medicine

In addition to Phase I through IV trials, the VCS Research Institute also studies novel approaches to medicine such as immunotherapy and vaccines. Immunotherapy is a type of treatment that uses the body's own immune system to fight disease. The VCS Research program also has several trials using precision medicine, a way of using specific drugs to target a patient's individual tumor mutations or molecular characteristics. Vaccine trials study how we can harness the body's immune system to help prevent a cancer from growing or coming back. VCS also has trials of the newest generation of drugs that target the EGFR and alk molecules. Although these approaches are experimental, and thus in clinical trial, they also offer patients and physicians new hope when other options fall short.

Sample Trials and Treatments



The VCS Research Institute offers many types of trials that help research targeted and novel therapies for different cancers.

Below are some cancers that are studied at the Institute:

- **Breast**
- **Gastric**
- **Head and Neck**
- **Leukemia**
- **Lung**
- **Lymphoma**
- **Melanoma**
- **Multiple Myeloma**
- **Pancreatic**
- **Prostate**
- **Squamous Cell**



Trials in Your Community

Virginia Cancer Specialists (VCS) has nine locations to serve you. Many of these locations offer clinical trials through the VCS Research Institute, making it even easier for patients to participate in the latest, ground-breaking research right in Northern Virginia.

ALEXANDRIA*

4660 Kenmore Avenue, Suite 1018
Alexandria, VA 22304
(571) 483-1800

FAIR OAKS

3650 Joseph Siewick Drive, Suite 200
Fairfax, VA 22033
(703) 280-5390

RADIATION ONCOLOGY CENTER

10301 Democracy Lane
Fairfax, VA 22030
(703) 934-4450

ARLINGTON*

1635 N. George Mason Drive, Suite 170
Arlington, VA 22205
(703) 894-3800

FAIRFAX*

8503 Arlington Boulevard, Suite 400
Fairfax, VA 22031
(703) 280-5390

RESTON

1860 Town Center Drive
Reston, VA 20190
(703) 437-6535

ARLINGTON INFUSION SUITE*

1701 N. George Mason Drive, Suite G-101
Arlington, VA 22205
(703) 894-3800

GAINESVILLE*

7901 Lake Manassas Drive
Gainesville, VA 20155
(571) 222-2200

WOODBIDGE

2280 Opitz Boulevard, Suite 300
Woodbridge, VA 22191
(703) 986-1600

LOUDOUN*

44035 Riverside Parkway, Suite 300
Leesburg, VA 20176
(703) 554-6800

*Currently participates in clinical trials. For a list of current trials and participating locations, please visit our website at VirginiaCancerSpecialists.com.



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