



Translating Research into Medicine

National Cancer Institute at Frederick

With our partners, we are developing faster and less expensive ways of turning laboratory discoveries into new diagnostic tests and treatments for cancer and AIDS.



From the Associate Director

The National Cancer Institute at Frederick (NCI-Frederick) is a unique national resource because it offers such a wide range of advanced technologies that are important to creating the next generation of therapies for cancer and AIDS. NCI-Frederick, which brings together scientists from the government, academia, and private industry, is positioned to facilitate public–private partnerships that will be vital to the future of the entire National Cancer Institute.

Craig W. Reynolds, Ph.D., Associate Director of the National Cancer Institute and Director of the Office of Scientific Operations of the National Cancer Institute at Frederick

National Cancer Institute at Frederick

A Federally Funded Research and Development Center

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National Cancer Institute at Frederick



NCI-Frederick partners with university, government, and corporate scientists to speed the translation of laboratory research into new diagnostic tests and treatments for cancer and AIDS.

With a unique array of advanced technologies, NCI-Frederick is bridging the gap between discovery and health-care delivery. We focus on projects that cannot be effectively achieved by other means. We assess research for its value to patients. We accelerate the development of new technologies and prototype treatments for patients. We also pave the way for new advances to enter clinical trials for testing, approval, and delivery to patients via the commercial sector.

Academic and government researchers locally and across the nation rely on NCI-Frederick to:

- Deliver pure prototype drugs for clinical trials with quick turnaround;
- Help win regulatory approval for new drugs, vaccines, and other therapies;
- Cut the cost of nanotechnology research through a standards-based evaluative approach;
- Produce large quantities of test vaccine with little lead time;
- Speed technology development and reduce costs through strategic partnerships;
- Improve the delivery of the latest, research-driven cancer care to people in their home communities;
- Support national data networks that keep researchers and caregivers up to date on the latest laboratory and clinical advances; and
- Advance the goal of personalized medicine in cancer and AIDS.



NCI-Frederick is designated by Congress as one of 39 Federally Funded Research and Development Centers. These U.S. national laboratories are government-owned, contractor-operated facilities that combine private business practices with government operations under a broad charter that promotes quick action, flexibility, and accountability to address urgent national priorities of the federal government.

Our campus, 50 miles north of Washington, D.C., is home to about 3,000 researchers, technology development teams, regulatory liaisons, and support personnel. This combination gives us a unique perspective that spans laboratory discovery, technology development, and health-care delivery.

With our collaborators, we are answering the call from Congress and the public to show how taxpayer investments in biomedical research are advancing medical treatments and helping patients.

NCI-Frederick quickly adapts to changing research and development advances to maintain a strategic focus and keep pace with new discoveries, development opportunities, and health-care priorities.



Genes, Beans, and Drugs

Finding What's Real, Functionally Speaking

Not all mutations are created equal. Some are silent, having no discernable effect on a cell, tissue, or organ, while others can be profoundly disruptive. Deciding which category a mutation fits into often requires a significant amount of experimental work and debate, particularly when the gene or genes in question could potentially raise or lower the risks of developing a disease like cancer.

Such is the case for the DNA repair genes *BRCA1* and *BRCA2*. Mutations in these genes can significantly increase a woman's risk of developing breast or ovarian cancer. While gene sequencing-based tests can help women assess risk and make appropriate decisions about prevention and treatment, the functional impacts of nearly 1,900 identified *BRCA1* and *BRCA2* mutations on the genes' protein products remain unclear. Tying mutations to functions would help improve breast cancer risk assessments; however, such functional studies are both labor- and resource-intensive.

Shyam Sharan, Ph.D., Head of the Mouse Cancer Genetics Program's Genetics of Cancer Susceptibility Section, in the Center for Cancer Research (CCR), and former Research Fellow Sergey Kuznetsov, Ph.D., developed an in-vitro functional assay system to measure the effects of *BRCA2* mutations accurately and relatively rapidly.

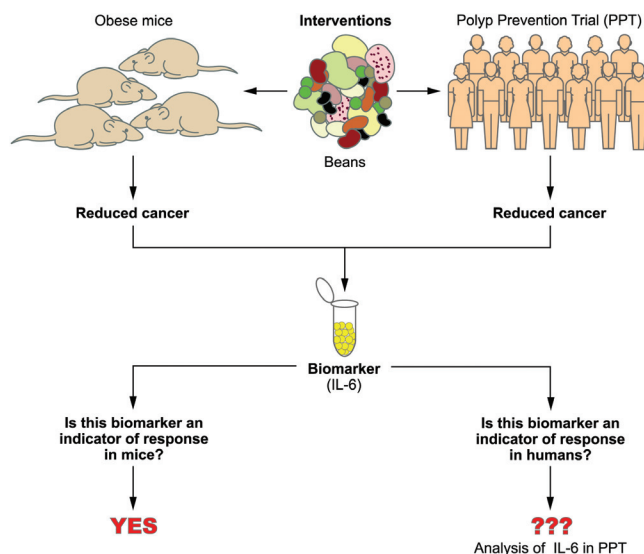
The system measures a mutation's influence on a cell's growth and survival and its sensitivity to agents that cause DNA damage. With this system, the researchers examined the functional impacts of 17 *BRCA2* mutations and were able to validate the known effects of 13 of those mutations. In addition, they found the first evidence of the consequences of four others that had not been previously characterized. The researchers noted that

the system could likely be used with numerous gene mutations, making it a potentially invaluable tool for genetic counselors. Further validation will be required, however, before the method can be applied in the clinic.

http://home.ccr.cancer.gov/connections/dev/2008/Vol2_No1/news_6.asp

A Diet That Works: New Study Shows Early Response of Colon Cancer to Dietary Change

Lifestyle plays an important role in human health, and conscious choices such as adopting more healthful dietary habits are crucial in 21st century health care to



Discoveries from the Polyp Prevention Trial suggested that a diet rich in beans would reduce the risk of colon cancer. Follow-up studies in mice proposed interleukin-6 (IL-6) as a biomarker of this response. Will IL-6 levels also reflect the efficacy of dietary intervention in humans? (Image: J. Kelly)

reduce spiraling costs. There is increasing support for learning more about diet and disease relationships, but setting up a clinical trial to test a dietary intervention is challenging. It is difficult to measure how well the intervention is working before actual disease onset.

In one of the first studies of its kind, Nancy Colburn, Ph.D., Chief of the Laboratory of Cancer Prevention at NCI's Center for Cancer Research (CCR), identified biomarkers of early response to an efficacious dietary intervention—whole navy beans and bean extracts—for reducing the development of colon cancer in genetically obese mice.

In a previous study, Dr. Colburn and colleagues had designed an experiment based on what had been observed in the Polyp Prevention Trial (PPT)—a human study that set out to determine whether a diet high in fruits and vegetables could reduce the recurrence of colon polyps (abnormal, potentially cancerous tissue growth) in at-risk individuals. The trial revealed that those who ate the highest amount of beans showed only a one-third recurrence rate. Dr. Colburn then designed a study using genetically obese mice injected with a substance to promote the growth of colon cancer, and placed the mice on a navy bean diet. She found reduced tumor growth in the mice that ate navy beans, compared with those mice not on the diet.

The new study tested tissues collected from the same mice for biomarkers that correlate with the efficacy of the diet. The research team found that the bean-fed mice had significantly lower inflammatory responses. This is a promising area of research for future prevention and treatment possibilities, since inflammation plays an important role in colon cancer.

“Biomarkers of response are important because we would like to match the intervention with those likely to respond. If we can identify after short-term exposures to the intervention those likely to respond, we can save a lot of time and money in human studies,” Dr. Colburn said.

http://home.ccr.cancer.gov/connections/dev/2009/Vol3_No1/news_3.asp



Chemical Biology Consortium

For more than 50 years, the NCI's Drug Discovery and Development Program has successfully guided drug candidates through the final steps of development to first-in-human studies. The Developmental Therapeutics Program has been involved in the discovery or development of more than 70 percent of the anticancer drugs currently on the market. Nevertheless, too few effective therapies exist for cancer, and moving a drug from concept to regulatory approval to patient takes too long. Experts also agree on the need for enhanced molecularly targeted drug discovery, and more streamlined processes to assess anticancer drug action early in development.

As part of its new strategic approach, NCI is emphasizing early drug discovery activities, specifically the application of high-throughput screening and medicinal chemistry to identify the most promising types of new anticancer and anti-HIV drugs. This initiative is the Chemical Biology Consortium (CBC).

The consortium focuses on identifying novel molecular targets and new molecules that link to those targets to support robust drug discovery and development. The CBC comprises an integrated network of medicinal chemists, chemical biologists, and molecular oncologists from government, industry, and academia with the resources, expertise, and experience to expedite development and testing of these promising new drugs.

The CBC is a component of NCI's Experimental Therapeutics (NExT) Program, which seeks to accelerate the discovery and development of effective first-in-class-targeted therapies for patients with cancer by providing the proper environment to identify new agents and facilitate their evaluation in the clinic. The program provides resources that are not readily available at most academic institutions or medical centers engaged in oncology research and drug development. Emphasis is placed on addressing unmet needs in therapeutic oncology, including “undruggable” targets, orphan malignancies, and pediatric cancers.

A Strategic Imperative

Translate Research into Medicine More Rapidly

At the heart of NCI-Frederick lies a strategic imperative to help patients. These days, it takes too long and costs too much to put a new cancer drug into the hands of someone with cancer or AIDS. On many fronts, NCI-Frederick is working to lower these costs and shorten the timeline for moving research discoveries out of the laboratory and into the service of patients.

To this end, NCI-Frederick is spearheading an intensive effort to advance new treatments for cancer and AIDS by forging strategic partnerships among NCI, other government agencies, life-science companies, nonprofit research organizations, and academic research and education institutions. Under this Advanced Technology Partnerships Initiative (ATPI), more than a dozen partnerships and collaborations have already been formed in areas ranging from nanotechnology to gene sequencing to advanced biomedical imaging.

Among these projects is an evaluation of nanomedicine for targeted drug delivery. The initial focus is on docetaxel, a drug widely used to treat a range of cancers, including lung, breast, and prostate. In another project, researchers are working to reduce the toxicity of cancer medicines with new technology to improve drug formulations.

To support the ATPI, a 330,000-square-foot research and development facility is under construction at Riverside Research Park in Frederick, Md. This expansion space will consolidate technologies and programs now spread among more than 30 buildings on NCI-Frederick's campus within the perimeter of Fort Detrick. The Riverside Research Park has space available for collocation with research and development partners, business incubators, high-tech company spinoffs, and a proposed higher education center for training the next generation of translational research scientists.



Another way to accelerate new cancer treatments is to pretest candidate drugs to ensure a high likelihood of success once they enter human clinical trials. NCI-Frederick has been instrumental in piloting a concept for prequalifying candidate drugs before they enter Phase I clinical trials. The approach is called Phase 0.



In Phase 0, a candidate drug is administered to a handful of volunteers to see if it will hit its target and have the intended effect. In the first-ever Phase 0 trial, NCI-Frederick provided support for testing a candidate compound, ABT-888, which hinders DNA repair in tumor cells after they are damaged by chemotherapy. The Phase 0 trial confirmed ABT-888's effectiveness and it moved into Phase I trials. It is now making its way through the three phases of clinical testing for U.S. Food and Drug Administration (FDA) approval.

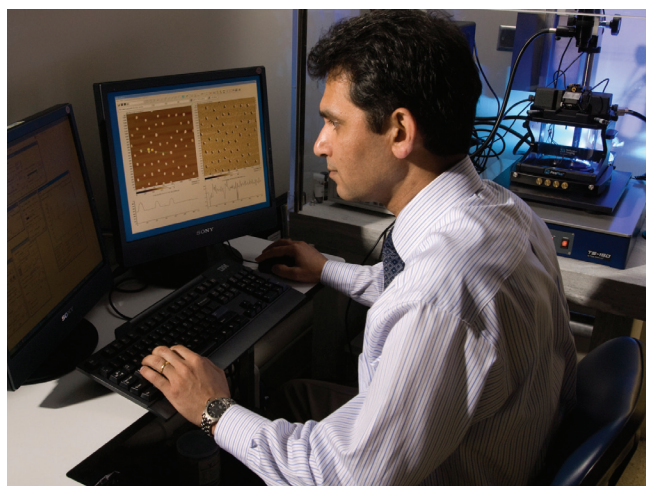
On another front, NCI-Frederick's Center for Advanced Preclinical Research is developing mice engineered to have a human immune system and to develop cancers

naturally. As a result, the animals provide a more realistic and accurate testing ground for new therapies.

One of the most recent ATPI partnerships includes the Jackson Laboratory to evaluate a candidate lung cancer therapy that targets multiple signaling molecules involved in cell growth. The treatment is being tested in a population of genetically engineered mice. If successful, the approach will be developed for screening a broad range of new therapies for lung tumors and will be made widely available to researchers across the country.

NCI-Frederick is accelerating the translation of nanotechnology-based cancer therapies into human clinical trials. The Nanotechnology Characterization Laboratory (NCL), part of NCI's Alliance for Nanotechnology in Cancer, has more than 50 collaborations with organizations using nanotechnologies to develop new diagnostic tests and effective, targeted treatments for cancer.

NCL—a partnership of NCI, the National Institutes of Standards and Technology, and the FDA—is currently working to thoroughly characterize more than 160 nanomaterials for possible use against cancer.



NCI-Frederick's Mission

To Provide a Unique National Resource...

The cutting-edge expertise and technologies of NCI-Frederick are available to partners, collaborators, and others, both within and outside of the government, for research and development.

In fact, the mission of NCI-Frederick is to “provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer and AIDS.”

Here is a summary of selected available resources. For a complete list, see <http://atp.ncifcrf.gov>.

Advanced Biomedical Computing

The Advanced Biomedical Computing Center focuses on supporting scientific research at NCI-Frederick, NCI-Bethesda, and the National Institutes of Health (NIH). It provides bioinformatics support in microarray analysis, genomic analysis, databases, second- and third-generation sequencing, and laboratory information management systems. The center provides scientific support in structural analysis of nanoparticles, viruses, and proteins; molecular modeling; biomedical imaging; biomarker discovery; scientific web applications; advanced computational algorithms; and alternative computing platforms.

<http://isp.ncifcrf.gov/abcc>

Gene Expression

The Laboratory of Molecular Technology provides gene expression capabilities using the Nanostring and Fluidigm platforms, copy number variation using the Affymetrix SNP 6.0 arrays, improved next-generation sequencing capabilities using the Fluidigm Access Array system, and methylation detection using the Pyromark platform. The Affymetrix Microarray Service offers state-of-the-art full services for gene expression and genotyping analysis, using microarrays/cartridges/chips in all of the major model organisms. It offers data analysis using Agilent CGH Analytics and other programs, and integration of array-CGH data with pathway analysis of gene expression data.

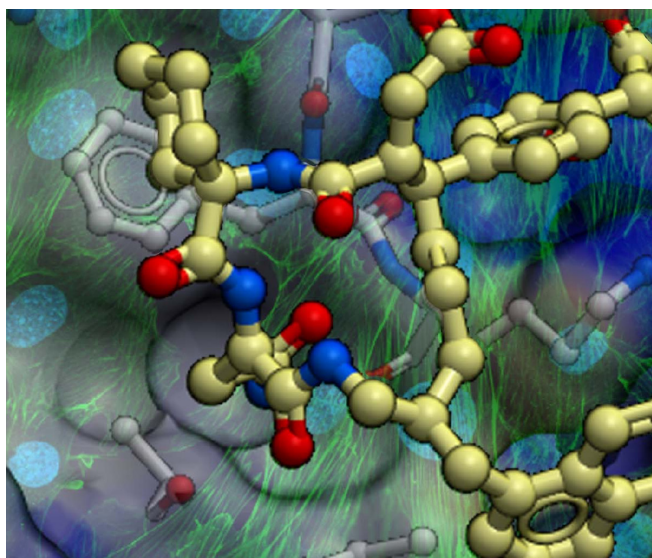
Genomics

The Genetics and Genomics Group's Sequencing Facility has placed an Illumina sequencer in operation and has upgraded the capabilities to include four Illumina GAIIx instruments and one HySeq instrument. Supporting personnel and equipment, including cluster generation stations and library preparation stations, provide the capacity for routine whole genome sequences. New single-molecule, third-generation sequencing capabilities from Pacific BioSciences, Inc., are being installed. The Sequencing Facility has also successfully installed and validated the Hiseq 2000, a next-generation sequencer from Illumina.



Imaging

The Electron Microscopy Laboratory provides a range of state-of-the-art microscopy support services to the NCI community for virus characterization, cell and tissue visualization, and molecular and nanoparticle analysis. The Optical Microscopy and Analysis Laboratory collaborates with NCI principal investigators on research in quantitative microscopy for understanding carcinogenesis in solid tumors and analysis of signaling pathway kinetics and molecular spatial organization in individual cells.



Protein Chemistry

NCI-Frederick has state-of-the-art, matrix-assisted laser desorption/ionization-time-of-flight (MALDI-TOF) mass spectrometry with MALDI-imaging capabilities, as well as ultra-high-mass detection. The MALDI Mass Spectrometry Group provides advanced technologies such as MALDI-imaging and high-mass determination of cross-linked molecular complexes. Advanced protein chemistry approaches have been used to develop a method for efficiently (practically quantitative) modifying antibody mimics by radioactive and fluorescent alkylating reagents.

Protein Expression

The Protein Expression Laboratory assists investigators in cloning, expressing, and purifying proteins important in human disease; delivering genes and gene products to mammalian cells through viruses and nucleic acids; developing assays of gene expression and protein expression in clinical samples; and developing new protein technologies.

Proteomics and Analytical Technologies

Proteomics involves protein identification, quantitative proteomics, metabolomics analysis, steroid hormone analysis, separation technologies, and assay development. The Laboratory of Proteomics and Analytical Technologies maintains a translation effort to integrate expertise to bear on research problems related to protein interactions and signaling and continues to expand capabilities by developing multiple-reaction monitoring assays to quantitate proteins in biologic samples.

Nanotechnology Characterization

The Nanotechnology Characterization Laboratory (NCL) at NCI-Frederick is an international leader in testing nanomaterials for biomedical applications. NCI established the laboratory in 2004 as part of its Alliance for Nanotechnology in Cancer. The laboratory is a collaboration with the U.S. Food and Drug Administration and National Institute of Standards and Technology. NCL performs preclinical characterization of nanomaterials intended for cancer diagnostics or therapeutics. The laboratory selects nanomaterials to characterize based on an application process (applications are evaluated on published criteria, with a focus on demonstrated proof-of-concept anticancer efficacy and potential for clinical translation), which allows it to support the most promising and innovative nanomedicines.

<http://ncl.cancer.gov>

Biopharmaceutical Development

The Biopharmaceutical Development Program (BDP) was established in 1993 to provide dedicated services to intramural and extramural NIH investigators, government agencies, and independent parties through interagency agreements or cooperative research and development agreements. BDP provides leading-edge development of monoclonal antibodies, recombinant proteins, peptide and DNA vaccines, virus vaccines and oncolytic viruses, gene therapy products, and other biological agents. It maintains biopharmaceutical production and testing facilities that are compliant with relevant current Good Manufacturing Practices.

<http://web.ncifcrf.gov/research/bdp>



Laboratory Animal Sciences

The Laboratory Animal Sciences Program (LASP) represents a comprehensive resource for NCI's animal research programs on both the Frederick and Bethesda campuses, with the aim of providing the highest quality animal care and animal support services possible for investigators performing animal-based research.

<http://web.ncifcrf.gov/rtp/lasp/intra>

Mouse Models of Human Cancers

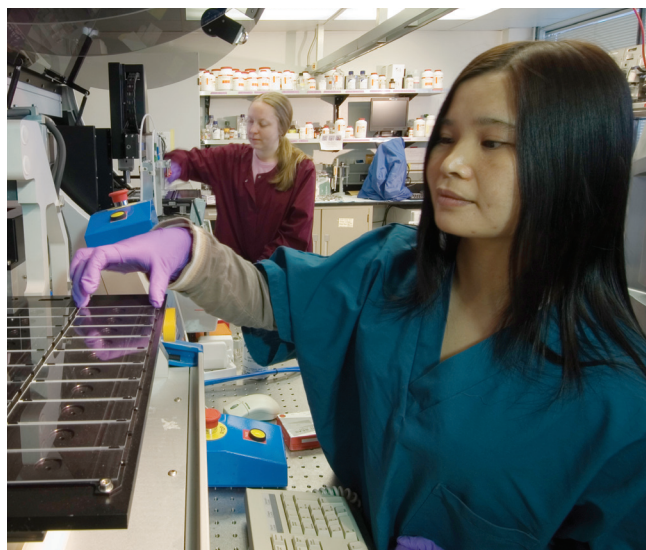
Mouse models of human cancers provide an ideal experimental system for studying tumor biology within the physiological milieu. Research utilizing these models has produced essential insight into cancer biology, including tumor–host cell interactions, the function of stem cells in cancer progression, the function of oncogenes and tumor suppressor genes, and the factors that influence cellular responsiveness to chemotherapeutic agents.

<http://mouse.ncifcrf.gov>

Small Animal Imaging

The Small Animal Imaging Program was established to provide state-of-the-art in vivo imaging capabilities to fulfill the requirements of NCI researchers. Functions include assisting NCI investigators in developing mouse models and new targets for early detection and therapy, and testing potential new therapies without sacrificing the animal. The laboratory provides optical and ultrasound imaging, PET imaging, MRI and other technologies, and has the expertise to support a wide range of research.

<http://web.ncifcrf.gov/rtp/lasp/intra/saip>



Biological Resources

The Biological Resources Branch is an extramural arm of NCI's Developmental Therapeutics Program. It supports preclinical and early (e.g., Phase I) clinical studies of biological response modifiers and research in the biomedical community through a program of grants and contracts. These studies assess the effects of novel biological agents and explore the relationships of biological response and antitumor activity.

<http://web.ncifcrf.gov/research/brb>



Central Repository

Central Repository Services provide NCI and the research community with various cryogenic services, including low-temperature storage from +4°C to -196°C, controlled-rate freezing, computerized inventory, and sample distribution.

<http://web.ncifcrf.gov/repository/cr>

Natural Products

Out of approximately 170 antitumor drugs approved worldwide since the 1930s, more than 65 percent are derived from natural products—ranging from deep-sea sponges to the flowers and insects of our planet's jungles and rainforests. NCI has committed itself to conserving this rich biological diversity and adopting policies of fair and equitable collaboration and compensation in interacting with the source countries participating in collection programs for the Natural Products Repository. Agreements based on the NCI Letter of Collection have been signed with relevant government organizations in many of the source countries participating in the collection program. NCI considers the Natural Products Repository a national resource. Extracts from the repository are available either in vials or in 96-well plates for distribution to qualified organizations.

<http://dtp.nci.nih.gov/branches/npr/repository.html>

Tumor Bank

NCI's Division of Cancer Treatment and Diagnosis has maintained, since the early 1960s, a low-temperature repository of transplantable in vivo-derived tumors and in vitro-established tumor cell lines from various species. The Tumor Repository serves as a resource for viable, contaminant-free experimental tumor lines, many of which cannot be obtained elsewhere. The repository makes these materials available to qualified investigators as a service to the research community.

<http://dtp.nci.nih.gov/branches/btb/tumor-catalog.pdf>

Assay Development and Validation

The newly established Patient Characterization Center (PCC) and Clinical Assay Development Center (CADC) are part of NCI's Clinical Assay Development Program (CADP). The goals of PCC include the application of standardized assays using genomic technologies such as genome-wide gene expression profiling and next-generation sequencing to verify biomarker discoveries and generate a high-quality database to support cancer treatment. CADC, as part of the Clinical Assay Development Network, will offer services to support successful applicants in clinical assay development and validation.

http://plan.cancer.gov/Patient_Characterization_Center.htm

High-Quality Clinical Research Support Worldwide

Through its Clinical Group, NCI-Frederick provides high-quality clinical trials management, regulatory support and quality assurance for the production of vaccines and biological agents for clinical testing. This includes support for clinical trials being conducted by both the National Cancer Institute and the National Institute of Allergy and Infectious Diseases, both part of the U.S. National Institutes of Health.

NCI-Frederick's Clinical Monitoring Research Program supports about 350 domestic and international clinical trials at sites throughout the United States and overseas, including sites in Europe, South America, Canada, Southeast Asia, and Africa.

Support for clinical trials has expanded significantly over the past seven years, with a focus on quality clinical research, compliance with applicable regulations and guidelines, and assurance of data integrity—with the priority goal of protecting human subjects.

The program has been instrumental in developing and undertaking new trial designs, including the recent single-agent phase II trial with ADZ2171 (Cediranib) – a promising regimen for treating alveolar soft-part sarcoma, a rare, slow-growing tumor of soft tissues that affects mainly children and young adults and often migrates to the lung or brain.

The program also recently designed a multi-histology phase II trial with R788 for patients with advanced cancers of the colon, thyroid, lung (non-small cell), liver, head, neck, and kidney.

Among other recent initiatives, the clinical program has supported several major initiatives of the Office of Biorepositories and Biospecimen Research and NCI efforts to provide leadership and standardization in the collection, storage, and transmission of biospecimens for cancer research. OBBR is developing a shared infrastructure for collaborations

and team science around multi-institutional, high-throughput genomic and proteomic studies in cancer.

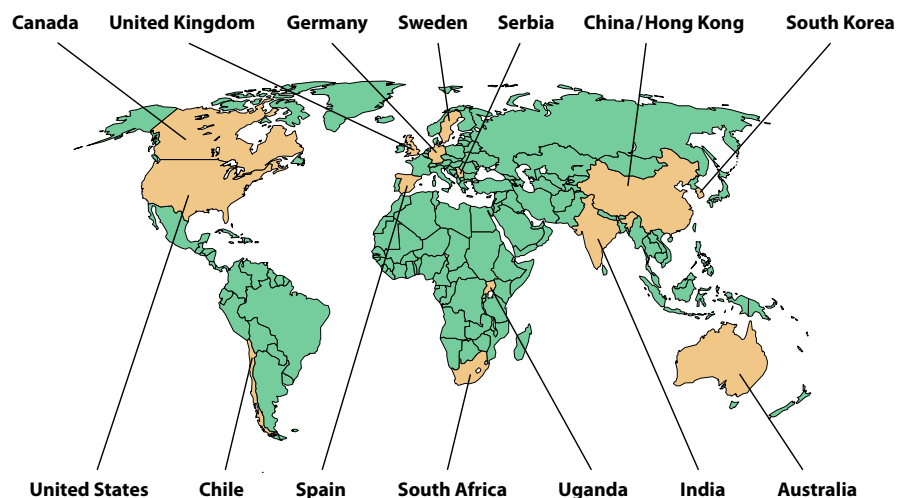
In support of the Tobacco Control Research Branch, the NCI-Frederick clinical program has assisted with two applications to the Facebook® Smokefree Women group.

With funding from the American Recovery and Reinvestment Act, the clinical program has managed the expansion of a network of community cancer centers to 30 sites in 22 states with the goal of bringing the latest research and technologies more rapidly into community practice and to involve more patients in research.

The NCI Community Cancer Centers Program aims to:

- Reduce health care disparities by reaching underserved populations
- Draw more adult patients into early-phase clinical trials
- Explore standards for voluntary donation of blood and other specimens for research
- Evaluate the use of electronic medical records.

NCCCP hospitals are collaborating with NCI's existing network of 63 designated cancer centers located at major research institutions, which lead the way in developing new cancer treatments.



In the Community

NCI-Frederick and its prime contractor, SAIC-Frederick, Inc., are actively involved in nurturing the community in which their employees live and work. The contractor supports a wide cross-section of nonprofit organizations and charities. SAIC-Frederick also manages a program through which its employees make charitable contributions through payroll deduction, with the company matching those donations dollar-for-dollar up to a set limit. The contractor plays leadership and supporting roles in advancing local business and economic development and is committed to being actively involved at the city, county, and state levels. NCI-Frederick sponsors a series of educational programs that reach from grade school through graduate school. Both NCI-Frederick and SAIC-Frederick are members of the Frederick County Chamber of Commerce.

Selected Community Sponsorships and Donations (via prime contractor, SAIC-Frederick, Inc.)

- Education
- Business
- Health
- Science
- Charity
- Culture
- Scientific Sponsorships

Employee Volunteer Activities, Contributions to:

- American Cancer Society, Heartly House
- American Cancer Society Road to Recovery
- Hospice, United Way agencies, Food Drives, Frederick Memorial Hospital
- Frederick Reads, Frederick County Community Foundation, Frederick County Cancer Coalition
- Susan Komen Race for the Cure
- Children's Inn at NIH

NCI-Frederick Educational Outreach Programs

- Elementary Outreach Program
- Werner H. Kirsten Student Intern Program
- Cancer Research Training Award Program—Primarily college undergraduates
- NCI-Frederick Spring Research Festival Program
- Take Your Child To Work Day
- NIH Speakers Bureau—Available to local schools, other groups
- NCI-Frederick Employees—Adjunct faculty at local colleges and universities
- Frederick County Workforce Services Summer Jobs Program
- Evening classes at NCI-Frederick—NCI-Frederick hosts evening classes from educational institutions, including, but not limited to, University of Maryland University College (UMUC) and University of Maryland Baltimore County (UMBC). These classes are open to all NCI-Frederick employees.

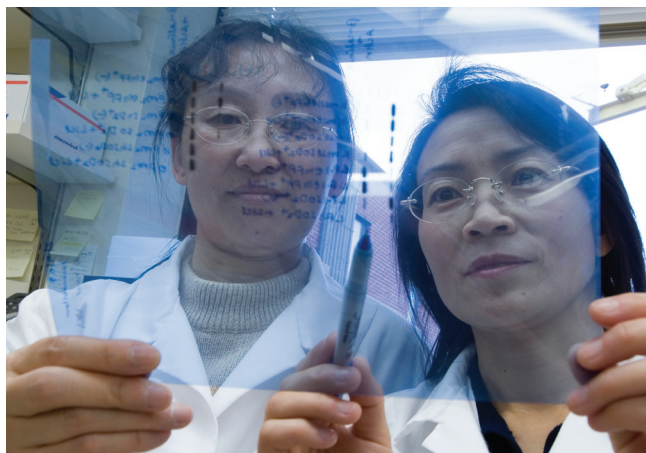


NCI-Frederick Support to Investigators at Other NIH Institutes, in Academia, and at Other Government Agencies

Since 2005, NCI-Frederick has provided scientific support to 25 of the 27 NIH institutes and centers, and seven other government agencies. Moreover, as a national resource for biomedical research focused on cancer and AIDS, NCI-Frederick has provided research support to academic and nonprofit research institutions nationwide. NCI-Frederick has:

- Provided state-of-the-art computational services to more than 100 non-NCI investigators in academia and at other government agencies through its Advanced Biomedical Computing Center.
- Evaluated more than 180 nanotechnologies through material transfer agreements with more than 65 extramural investigators through its Nanotechnology Characterization Laboratory, part of the NCI Alliance for Nanotechnology in Cancer.
- Provided more than 900 services—including electron microscopy, high-throughput DNA sequencing, protein expression and purification, microarray analysis, and real-time PCR—to 295 researchers from government and academia during the past five years.
- Fulfilled more than 1,300 requests for animal science services from government researchers in the National Institute of Allergy and Infectious Diseases (NIAID); the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); the National Institute of Dental and Craniofacial Research (NIDCR); the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); the National Human Genome Research Institute (NHGRI); the National Institute of Neurological Disorders and Stroke (NINDS); and the Uniformed Services University of the Health Sciences (USUHS).
- Conducted 266 transgenic and knockout mouse production and embryonic stem cell injections in support of federal research institutes.

- Performed 183 embryo cryopreservation and reconstitution projects through its Cryopreservation/ Assisted Reproduction Laboratory for NIAID, the National Institutes on Aging, and other agencies.
- Conducted 28 speed congenics projects for NIH institutes, including NIAID, NIDDK, and NINDS.

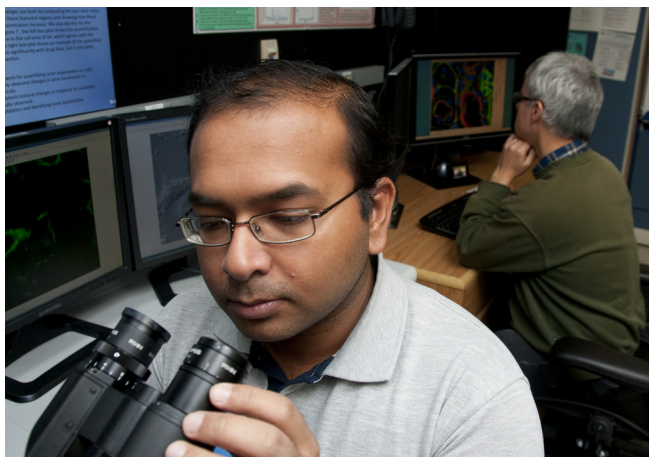


- Distributed about 15,000 genetically engineered mice throughout the international scientific community through the Mouse Models of Human Cancers Consortium Repository.
- Distributed more than 5 million high-quality research animals to investigators at more than 235 institutions, including academic centers such as the Johns Hopkins University, Yale University, Dartmouth College, the University of Iowa, University of Texas MD Anderson Cancer Center, and the Southern Research Institute.
- Shipped free of charge more than 9,000 unique research products annually to the extramural research community, including antibodies, assay kits, cell lines, plasmids, recombinering reagents, viruses, natural products, and cytokines.
- Provided more than 26,800 HIV and SIV Capsid Protein Antigen Capture Assay Kits to more than 370 extramural researchers—at a cost savings of about \$47 million.

- Provided 3,300 mL of concentrate, purified viruses and related reagents to 167 outside investigators— at an estimated cost savings of about \$3.3 million. NCI-Frederick’s AIDS and Cancer Virus Program is the primary, and sometimes only, source of purified recombinant nucleocapsid proteins from a variety of wild-type and mutant retroviruses.
- Provided millions of dollars worth of high-quality research reagents (some of which are unavailable commercially), including cytokines, monoclonal antibodies, cytokine reference standards, recombinering reagents, and reagents for apoptosis imaging and signal transduction. These are provided at no cost to extramural investigators and qualified commercial establishments.
- Provided more than 5,757 human-tumor-cell-line vials, 1,920 Tissue Array Research Project microarray slides, and 3,000 molecular target cell pellet vials to the extramural research community through the Division of Cancer Treatment and Diagnosis (DCTD).



- Became the nation’s sole producer of the ch14.18 monoclonal antibody, part of the newest standard of treatment for children with high-risk neuroblastoma. (The technology is being transferred to a commercial producer.)
- Executed more than 5,000 material transfer agreements with the extramural research community, each providing a unique biological material/research service.
- Hosted more than 263 visiting scientists, guest researchers, and volunteer scientists, all with master’s degrees or higher.
- Provided more than \$54.5 million worth of services to 331 researchers supported by NCI or NIAID to test innovative treatments for cancer, AIDS, and other infectious diseases in national and international locations. These include support to:
 - The Translational Research Initiative, Cancer Therapy Evaluation Program (CTEP), DCTD, NCI —Management of 300 research agreements (273 subcontracts plus 27 additional basic ordering agreements) to 51 extramural institutions.
 - The Cancer Diagnosis Program, DCTD, NCI —Management of 18 research subcontracts to 12 institutions.



- Released more than 70 lots of clinical-grade biopharmaceuticals to the NCI intramural and extramural programs for use in toxicology or clinical studies.
- Manufactured clinical products for NIAID, NIDDK, and the U.S. Army Medical Research Institute for Infectious Diseases.

- The Cancer Imaging Program, DCTD, NCI—Provision of comprehensive regulatory and clinical trials management support to six domestic clinical trials through awarded research agreements; management of 73 awards (59 subcontracts plus 14 basic ordering agreements).
- The Behavioral Research Program (BRP), Division of Cancer Control and Population Sciences (DCCPS)—SAIC-Frederick provides innovative solutions to DCCPS projects for process improvement and adaptations of technology through the management of two subcontracts and 30 consulting/professional services agreements. Initiatives include Smokefree.gov, the North American Quitline Consortium, the National Network of Quitlines, and developing scientific meetings related to tobacco cessation, cancer care, the Tobacco Research Network on Disparities (TReND), and the Health Information National Trends Survey (HINTS).
- NCI and NIAID—Provision of comprehensive regulatory and clinical trials management support to over 325 domestic and international clinical trials, including cancer, avian flu/severe human influenza, HIV, malaria, parasitic diseases, and other disease states. The fiscal year 2010 total NCI budget is \$12.6 million; the total NIAID Division of Intramural Research (DIR) and Division of Clinical Research (DCR) budget is \$40.6 million; and the total Clinical Center (CC) budget is \$1.3 million.



- NIAID DCR, DIR, and CC projects—Oversight of 27 subcontracts, which include clinical research site management, clinical monitoring, engineering, research testing, and clinical research training to support NIAID clinical sites, including Korea, China, India, Thailand, Vietnam, Taiwan, India, Uganda, South Africa, the University of Minnesota INSIGHT network, District of Columbia AIDS clinics, and other domestic contracts with sites in the United States.



- The Uniformed Services University of the Health Sciences (USUHS) Infectious Disease Clinical Research Program (IDCRP)—Provided clinical study oversight and clinical trial management of 44 protocols in various stages of development within IDCRP. The Clinical Monitoring Research Program's (CMRP's) Physician III serves on the Scientific Review Board to ensure the scientific validity of protocols before sending them to the Institutional Review Board (IRB). CMRP staff has aided Department of Defense staff in developing an infectious disease-specific IRB.

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