National Cancer Institute

The Nation's

Investment

in Cancer Research

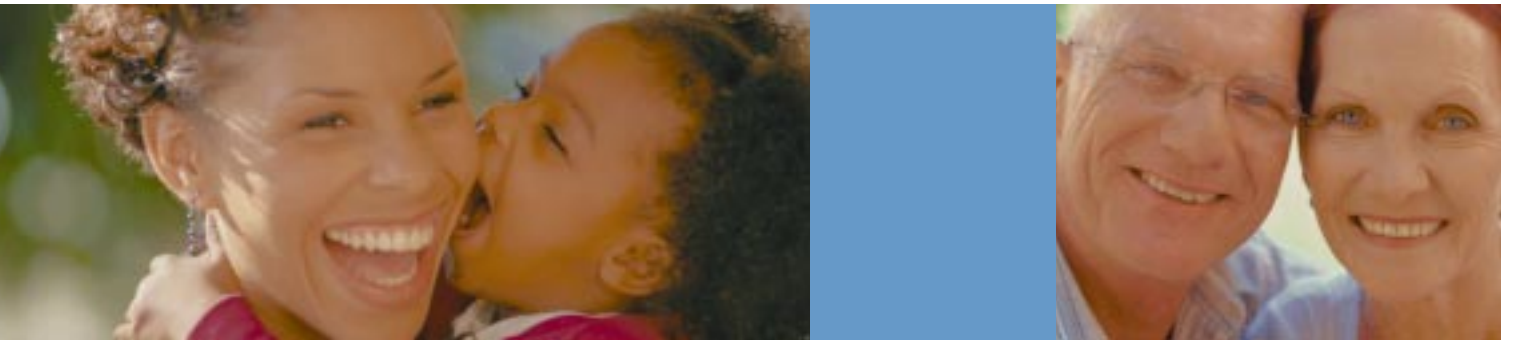
A Plan and Budget Proposal for Fiscal Year 2007

Prepared by the Director, National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Our Challenge Goal to the Nation:

Eliminate the suffering and death due to cancer by 2015



Director's Message

Excitement continues to build across the cancer community about the progress we are making toward our Challenge Goal to eliminate the suffering and death due to cancer by 2015! Continued advances in high throughput computing, bioinformatics, imaging technology, nanotechnology, genomics, proteomics, and computational modeling are paving the way for new discovery and accelerated intervention development and delivery. Collaborative efforts are streamlining the availability of tissue specimens, microarrays, image libraries, and epidemiological data. Newly established partnerships with other agencies within the Department of Health and Human Services, with other Federal and state agencies, and with the private sector are helping us all to leverage limited resources and to join together to ensure timely delivery of new cancer interventions to patients and people at risk. We have enormous responsibility in a time when resources are more precious than ever.

NCI staff are working daily to facilitate new opportunities for both individual and interdisciplinary team research to flourish. We are working to carry out the recommendations of the Clinical Trials Working Group and supporting a similar effort on Translational Research, both supported by the National Cancer Advisory Board. We are implementing more robust and integrative programs in cancer imaging, bioinformatics, and health disparities. We are working with internal and external stakeholders to identify needs and plan strategies related to specific diseases like lung cancer and groups of cancers, such as those that disproportionately affect our adolescent and young adult population.

In this budget proposal for Fiscal Year 2007, we describe five high impact areas requiring an infusion of resources in order to maximize our ability to move forward. Each is essential for us to not only accelerate our progress against cancer but to also contribute to the overall health of our Nation. Our investments in health information system technology, for example, can serve as a model and pilot for broader application to the national effort. Our leadership in bridging technology and science and in facilitating interdisciplinary research will help to strengthen a new integrative science paradigm across the entire biomedical community.

We as a Nation will succeed when everyone works in close harmony to relay cancer information and ensure the adoption of evidence-based interventions. We must help all of our citizens maintain healthy lifestyles, get screened regularly, obtain prompt treatment when cancer is diagnosed, and have access to quality follow-up care. Researchers across many disciplines, technology experts, public health specialists, healthcare providers, patients, people at risk, and healthy people must work to define and do their part. People all over the world demonstrate their ability to overcome the odds every day. Cancer will be no exception.

Andrew C. von Eschenbach
October 2005

The Nation's Investment in Cancer Research:
A Plan and Budget Proposal for Fiscal Year 2007

This plan and budget proposal for Fiscal Year 2007 describes continuing and new activities that, in the best judgment of the leadership of the National Cancer Institute, will accelerate achievement of our Challenge Goal to eliminate the suffering and death due to cancer. Our Annual Report for 2004, *The Nation's Progress in Cancer Research*, highlights just a few of the many recent scientific and programmatic advances we have seen in our fight against cancer. Later this fall, we will also publish our long-range NCI Strategic Plan for leading the Nation to achieve our Challenge Goal.

NCI engages in a number of ongoing planning and priority setting activities to ensure that we are responsive to new discoveries and opportunities and maximize use of our resources. NCI staff work with researchers and other representatives from the scientific, medical, and advocacy communities to determine what is needed and how best to move the science forward. We keep our research portfolio balanced and our support structure strong through ongoing program assessment and response to recommendations arising from those assessments. We convene scientists from diverse settings to work with NCI staff in developing new initiatives and redesigning programs. We track implementation and report regularly on our progress.

Our planning activities encompass three key components required for a strong cancer research enterprise:

Capitalizing on powerful scientific opportunities

We continually assess our portfolio and plan for research needed to uncover molecular characteristics common to different types of cancer and those that are unique to specific cancers. We seek those opportunities that hold greatest promise for accelerating the prevention, control, early detection and diagnosis, and effective treatment of the disease.

Targeting specific public health needs

As we assess our Nation's progress in addressing critical issues, we focus investments in areas such as tobacco and tobacco-related cancers; energy balance and the importance of diet, exercise, and weight management; health related quality of life for cancer patients and survivors; the quality of cancer care; and cancer health disparities.

Maintaining a sound research infrastructure and building capacity for the future

We give priority to developing the investigational, technological, and personnel resources needed to support changing needs and the translation of evidence-based interventions into clinical practice.

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NCI Budget Request for Fiscal Year 2007

Where We Stand Today

The national investment in cancer research is making a difference in the lives of Americans every day. However, cancer remains one of our most urgent health concerns and the disease many fear most. This year, more than 1.3 million new cancer cases will be diagnosed and more than a half million people will succumb to the disease.

What the Statistics Tell Us

Overall cancer mortality continues the gradual decline that began in the early 1990s. Deaths from some of the most common cancers—colorectal, breast, and prostate—have declined faster. Lung cancer mortality among men also is falling, and the rate for women is stabilizing. These achievements can be traced to research that has produced better imaging and other diagnostic tools, along with more effective treatments. Information dissemination, a key component of NCI's mission, has improved public understanding of the disease and motivated the increased use of cancer screening tests and adoption of lifestyle changes that minimize cancer risk.

Today, nearly 10 million people are living with a cancer history. Of this growing population, 1.5 million were diagnosed more than 20 years ago. This means that people who develop cancer are living longer and with a better quality of life than ever before. More than two-thirds of people diagnosed with cancer can now expect to live for five years or longer. For children diagnosed with cancer, five-year overall survival now exceeds 75 percent. Increasingly, we are finding cancers at earlier, more curable stages, and our ability to control cancer symptoms that affect quality of life has improved.

The Continuing Need for Research

More than ever before, we understand that cancer is a varied and complex disease. Likewise, our success in preventing, treating, and ameliorating the effects of specific cancers is varied. Despite intensive efforts, we have made marginal progress against the most intractable cancers, such as pancreatic, lung, and liver cancers. For reasons not well understood, the incidence of certain malignancies — including adenocarcinoma of the esophagus, multiple myeloma, and kidney cancer — is rising.

Research also demonstrates that some populations, most notably minorities and the poor, continue to bear a disproportionate cancer burden. Lack of insurance or a steady source of care and sociodemographic limitations are factors that often result in lower utilization of screening services and late diagnosis in these populations. Cancer mapping is helping to target cancer control efforts by revealing — down to the county level — geographic areas in which incidence and mortality for specific cancers are exceptionally high.

Adolescents and young adults with cancer have been an understudied group that has experienced little or no gain in survival rates and whose needs for tailored treatment regimens and psychosocial support are now being recognized. Some evidence suggests that certain cancers common in this age group may have important biological differences compared with the same disease in an older adult.

Further, the risk of being diagnosed with cancer increases with age. Currently, about three-fourths of all new cancer cases occur in people 55 years of age or older. By 2030, the population over age 62 will number almost 83 million, approximately twice its current size. As our population continues to age and life expectancy lengthens or remains constant, we must prepare for a dramatic rise in cancer incidence. By some estimates, the annual number of new cancer cases may double by 2050. It is therefore imperative that effective treatments and symptom control are available to all who need them, and we must develop reliable interventions that prevent cancers from occurring.

We still have much to learn about the most effective ways to reach diverse groups — including youth, the elderly, people of various ethnicities and cultures, rural residents, migrants, and people with limited literacy — with cancer services and related health messages. We must learn how to better communicate up-to-date information about cancer screening, prevention, and treatment, including palliative care, and to encourage the adoption of new interventions by community healthcare workers who provide the majority of cancer care and are responsible for encouraging cancer prevention and early detection behaviors by their patients.

NCI Maintains Several Sources of Information to Track the Status of Cancer and Cancer Research

Annual Report to the Nation on the Status of Cancer

First issued in 1998, this publication is a collaborative effort among the American Cancer Society, the Centers for Disease Control and Prevention, the National Cancer Institute, and the North American Association of Central Cancer Registries. It provides updated information on cancer rates and trends in the United States. NCI's Surveillance, Epidemiology, and End Results databases are a major source of information for this publication that can be found at seer.cancer.gov/report_to_nation.

Cancer Progress Report

This is a biannual NCI publication about our Nation's progress against cancer, including prevention, early detection, diagnosis, treatment, life after cancer, and end of life. The information is gathered through a collaborative effort with other key agencies and groups, such as the Centers for Disease Control and Prevention and the American Cancer Society. The report was first issued in 2001 and will be updated in late 2005. The 2003 update is available only online at progressreport.cancer.gov.

Surveillance, Epidemiology, and End Results (SEER)

The NCI SEER program currently collects and publishes cancer incidence and survival data from 14 population-based cancer registries and three supplemental registries covering approximately 26 percent of the U. S. population. The program is the only comprehensive source of population-based information in the United States that includes stage of cancer at the time of diagnosis and survival rates within each stage. The mortality data reported by SEER are provided by the National Center for Health Statistics and cover the entire U. S. population. Go to seer.cancer.gov.

Cancer Mortality Maps and Graphs

The Cancer Mortality Maps and Graph Web Site provides interactive maps, graphs (accessible to the blind and visually impaired), text, tables, and figures showing geographic patterns and time trends of cancer death rates from 1950–1994, for more than 40 cancers. Go to cancer.gov/atlasplus.

The Nation's Progress in Cancer Research

This annual NCI publication highlights recent scientific, technological, and programmatic advances resulting from NCI-supported programs. First published to highlight achievements in 2003, the latest report is available online at cancer.gov/nci-annual-report.

NCI Cancer Bulletin

The NCI Cancer Bulletin is a weekly publication available online from NCI. It provides updates on NCI activities, the research and clinical trials funded by the Institute, and other activities of the United States and international cancer communities. Go to cancer.gov/ncicancerbulletin.

The National Cancer Institute works to advance fundamental knowledge about cancer across a seamless and dynamic continuum of discovery, development, and delivery. We provide vision and leadership for NCI-funded researchers across the United States and around the world and strive to ensure that the results of research are used in public health programs and clinical practice to reduce the burden of cancer for all people.

Building on past discoveries and technological advances, we plan, conduct, coordinate, and support cutting-edge research and its application. We support the development of, access to, and use of new technologies by cancer researchers. We encourage creativity and innovation in all of our endeavors. We provide research training and career development opportunities and maintain support mechanisms and collaborative environments to link scientists with their colleagues and with critical technological and information resources. As leader of the National Cancer Program, we provide the public with scientifically sound cancer information using communication methods carefully designed to meet the needs and preferences of cancer patients, their families, and caregivers.

NCI supports a broad range of research to expand our understanding of cancer and develop improvements in prevention and care. Some investigators conduct basic laboratory research on genes that may cause cancer. Others are studying the incidence of cancer in specific populations, such as people of low socioeconomic status and former smokers. Still other scientists focus on translational research such as developing tests to identify patients who carry genes that may make them susceptible to cancer or conducting early clinical trials to determine the readiness of new preventive agents, diagnostic tools, or treatment drugs for full clinical testing.

The paragraphs that follow describe the NCI research portfolio and the multitude of resources that are currently available with NCI funding.

The Current NCI Portfolio

Preempting Cancer at the Earliest Opportunity

Continued discovery in etiology and biology and the subsequent development of interventions in prevention, early detection, diagnosis, and treatment will provide the means by which we can preempt the initiation and progression of cancer at every stage, from precancer through metastasis.

Understanding the Causes and Mechanisms of Cancer

NCI's etiology research focuses on identifying and understanding the origins and causes of cancer. Genetic, environmental, and lifestyle factors can all contribute to cancer development. Genetic factors may include inherited genes known to be involved in familial cancer syndromes and spontaneous mutations to genes involved in regulation of cell growth. Examples of environmental factors that may affect cancer development include exposures to radiation, organic solvents, asbestos, other pollutants, and infectious agents such as viruses or bacteria. Lifestyle factors that put people at risk include smoking, alcohol consumption, parity, sun exposure, diet, level of exercise, and obesity. NCI's research portfolio includes population studies that identify the cancer risks associated with interactions between susceptibility genes and environmental or lifestyle factors as well as biological studies to elucidate causal pathways. Other studies assess disruptions to normal cellular biology caused by the dynamic interaction of these risk factors. For example, increased production of free radicals and changes in levels of certain hormones and growth factors has been implicated in the development of certain cancers. NCI's cancer biology portfolio addresses the cellular and molecular mechanisms of cancer initiation, progression, and metastasis as well as normal biological functioning. The portfolio includes studies of abnormal chromosomes or genes, DNA damage or mutation, aberrant gene expression or protein function, epigenetic[1] changes, cancer causing viruses, angiogenesis[2], and the movement of cells within the body. Approximately 10 percent of the biology portfolio supports research to understand normal biology, especially at the cellular and molecular level. This research includes studies of cellular metabolism and growth, the structure and function of genes and proteins, developmental biology, and cell to cell interactions.

[1] Epigenetics refers to factors which influence the behavior of a cell without directly affecting its DNA or other genetic machinery.

[2] Angiogenesis is the growth of new capillaries, or microscopic blood vessels, to supply the circulatory needs of tissues.

Accelerating Progress in Cancer Prevention

NCI is dedicated to exploring new approaches to prevent the onset of cancer through a broad portfolio of prevention research. Our investigations support the identification of medical and behavioral approaches to cancer prevention that can be translated to public health settings. The majority of the prevention research portfolio addresses strategies for preventing or delaying the onset of cancer, including nutritional approaches, vaccination, and chemoprevention. Nutrition related research includes investigation of the role of nutrients and micronutrients on human health, the effects of nutrients or nutritional status on cancer incidence, and techniques for assessing dietary intake. Prevention vaccine research explores strategies to stimulate the immune system to attack infectious cancer causing

agents or tumor specific antigens and identifies effective vaccine delivery strategies. Chemoprevention research is focused on drugs that can be used to prevent development of a primary or secondary cancer. Approximately one quarter of our prevention portfolio supports investigation of behavioral factors that affect cancer risk and strategies to change these behaviors. These projects focus on risk factors such as poor diet, lack of physical activity, sun exposure, and tobacco use. A small proportion of the portfolio addresses complementary and alternative methods for cancer prevention, such as diet, herbs, and other supplements that are not widely used in conventional medicine, as well as biobehavioral techniques such as hypnotherapy, relaxation, meditation, spiritual healing, massage, and biofeedback.

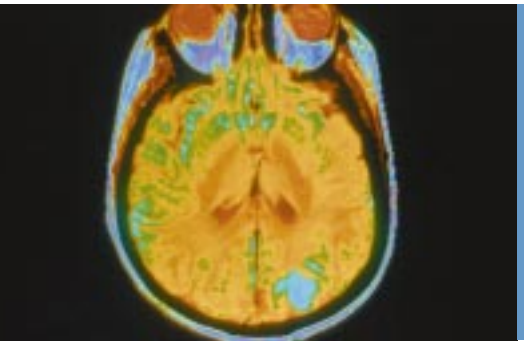
Improving Early Detection and Diagnosis

Much of this research portfolio focuses on the discovery and development of biomarkers and imaging techniques for cancer screening, early detection, diagnosis, and prognosis. Biomarkers are genes, proteins, or other molecules that indicate the presence of cancer based on their patterns or levels of expression. For example, prostate specific antigen (PSA) levels are used to

screen for prostate cancer. New research focuses on finding additional biomarkers for prostate cancer. Researchers are using proteomic technologies to develop biomarker panels to detect insidious cancers, such as ovarian and pancreatic cancer. Similarly, anatomical and molecular imaging techniques are used to detect tumors, inform prognosis, and identify metastasis. Promising new biomarkers or imaging technologies undergo preclinical evaluation before advancing to Phase I clinical trials for preliminary safety and efficacy testing. Later stage clinical trials evaluate biomarkers or imaging techniques for clinical specificity, predictive value, quality assurance and quality control, reproducibility, and effectiveness in reducing morbidity and/or mortality. This portfolio also supports research to determine how patients accept and comply with cancer screening methods.

Developing Effective and Efficient Treatments

A large part of NCI's research portfolio focuses on the discovery, development, and evaluation of therapeutic strategies for destroying cancer cells or modulating and controlling metastasis. These include localized, systemic, molecularly targeted, combination, or alternative approaches that do minimal harm to healthy tissue. Localized therapies, such as surgery or radiotherapy, directly target the tumor and sometimes neighboring tissue. Systemic therapies are usually administered intravenously or orally and include cytotoxic or hormonal agents, vaccines, antibodies, gene therapy, angiogenesis inhibitors, and differentiating agents. Molecularly targeted therapies are usually administered systemically, but are designed to interact specifically with the tumor and associated tissues. Combination therapies use two or more drugs and/or treatment



modalities to increase treatment efficacy. NCI also conducts research on complementary and alternative treatment approaches. New intervention strategies emerging from the treatment research portfolio are first evaluated preclinically and then moved sequentially through Phase I, II, and III clinical testing.

Ensuring the Best Outcomes for All

The successful application of evidence-based interventions for preempting cancer through prevention, detection, diagnosis, and treatment depends on our ability to move effective interventions into practice. NCI works with others to ensure that the results of our research and development efforts are adopted, that they accomplish their intended purpose, and that they adequately address issues in quality of cancer care, survivorship, and health disparities.

Improving the Quality of Cancer Care

NCI's portfolio includes critical research on the quality of care provided to cancer patients. This portfolio covers the discovery, development, measurement, and dissemination of interventions aimed at improving the quality of cancer care and health related outcomes across the cancer continuum. Quality of care research includes refinement of process and outcome measures, including the development of assessment metrics. Research on patterns of care include studies that link key data sources for tracking information on prevention and treatment interventions with NCI's surveillance programs. Other research focuses on understanding behavioral and sociocultural factors that influence the quality of cancer care, developing interventions that target the patient and their families, improving symptom management and palliative care, and training specialized care providers. Our quality of cancer care portfolio also supports use of claims data, design of functional evaluation tools, development of quality indicators for advanced cancer care, and dissemination of end of life resources to Cancer Centers. Researchers also evaluate patient psychosocial distress, the quality of supportive care for advanced cancer patients, and the impact of aging on quality of care.

Improving the Quality of Life for Cancer Patients, Survivors, and Their Families

Survivorship research focuses on the health and life of cancer patients following acute diagnosis and treatment phase and encompasses both the prevention and control aspects of chronic disease epidemiology. NCI's survivorship portfolio includes investigations into the broad spectrum of physiologic, psychosocial, economic, and behavioral effects of cancer and its diagnosis and treatment on survivors and their families with a strong emphasis on long-term and late effects. NCI supports both descriptive and intervention survivorship

research. For example, researchers study the genesis of recurrent cancer and second primary tumors, late effects of cancer treatment, and strategies for the early detection of residual disease in adult cancer survivors. Because breast cancer survivorship is most prevalent, the majority of studies examine the long-term and late effects related to this disease. In addition, pediatric cancer survivorship research is well represented in the research portfolio and a large portion of this research focuses on survivors of childhood acute lymphocytic leukemia.

The Center to Reduce Cancer Health Disparities

The Center to Reduce Cancer Health Disparities seeks to integrate studies across NCI research divisions in order to identify scientific and policy areas that provide opportunities to reduce cancer health disparities. In addition, the Center supports investigations to define and monitor disparities; develop and implement new policy, community and clinical interventions, and evaluate their impact; and expand minority participation, both as investigators and as patients, in health disparities research and clinical trials. Current initiatives illustrate the central importance of the Center's work.

The **Community Networks Program** expands upon the highly successful Special Populations Networks program to reduce cancer disparities through community-based participatory cancer education, training, and research among racial and ethnic minorities and underserved populations. Interventions include cancer prevention activities such as proven approaches for quitting smoking, increasing healthy eating and physical activity, and early detection and treatment of breast, cervical, and colorectal cancers.

The **Patient Navigator Research Program** represents a new approach to providing individualized assistance to patients, survivors, and their families. The Program places patients in contact with trained health care workers—or "navigators" who assist those in need of cancer care services. The overall goal of this program is to develop innovative patient navigator interventions designed to decrease the time between a cancer-related abnormal finding, definitive diagnosis, and delivery of quality standard cancer care services.

Overcoming Cancer Health Disparities

It is well known that many population groups across the United States and around the world suffer disproportionately from cancer and its sequelae. Gender, ethnicity, and socioeconomic status are among the major factors that influence disparate rates of cancer incidence, morbidity, and mortality. Areas in which cancer health disparities are particularly evident include

reduced access to cancer screening and diagnostic services, treatment disparities, lack of awareness about cancer risk and prevention, lack of access to clinical trials, and differential exposures to cancer causing agents. NCI efforts focus on improving the status of economic, social, cultural, psychologic, behavioral, and biologic factors that contribute to cancer health disparities. Research in NCI's biology, etiology, prevention, detection, and treatment portfolios addresses many of these issues. Resources and infrastructure necessary for disparities research include informatics, specimen resources, clinical trial groups, statistical methodology, drug and reagent resources, centers, consortia, and education and training of people prepared to work in careers focused on cancer health disparities. NCI's investments are accelerating the development and application of interventions for overcoming disparities across the cancer control continuum and among all underserved populations.

Our Research Infrastructure and Support

A considerable portion of NCI's budget is dedicated to building the capacity of the cancer research enterprise by providing infrastructure, resources, and other support. We focus on the support essential to carrying out cancer research and intervention development and promoting and learning from their delivery. Our intramural and extramural programs, NCI-supported Cancer Centers and Centers of Excellence, and various networks, consortia, and other partnerships all facilitate the development of and access to vital resources. We also support education and training programs for investigators and clinicians at all levels of experience and provide vital patient education services.

NCI Extramural Program

The largest portion of NCI research funds goes to supporting the work of scientists conducting research in universities, teaching hospitals, and other organizations outside the National Institutes of Health. Proposals submitted by these extramural investigators are selected for funding by peer review, a process by which cancer experts from around the country identify the best science and most needed areas of discovery by evaluating the approximately 5,000 new research proposals we receive every year. With guidance and oversight from program experts in NCI's Divisions of Extramural Activities, Cancer Biology, Cancer Treatment and Diagnosis, Cancer Prevention, and Cancer Control and Population Sciences, cancer research is conducted with NCI funding throughout the United States and in more than 20 other countries.

The Division of Extramural Activities (DEA) provides high quality scientific peer review of proposed extramural research as well as systematic surveillance of active awards to ensure a balanced research portfolio. This portfolio includes over 7,000 research and training awards across the spectrum of discovery, development, and delivery. Other portfolio components address long-term survivorship, rehabilitation, and end-of-life issues. In addition, DEA serves as a focal point for information about NCI's peer review and grants policies. DEA staff provide advice and guidance to potential applicants about grant policies and procedures, refer incoming grant applications to appropriate programmatic areas within the NCI, coordinate and administer most advisory board activities, and establish and disseminate extramural policies and procedures.

The Division of Cancer Biology (DCB) manages a diverse portfolio of grants, cooperative agreements, and contracts to advance the science of cancer biology. DCB scientists and staff work with individual investigators, professional societies, and research institutions to provide

information, advice, and guidance on a variety of research opportunities. Discussions, meetings, workshops, and conferences are among the mechanisms DCB uses to identify and address needs in various scientific areas. DCB uses a variety of communication media to keep the scientific community abreast of areas of special interest and scientific opportunity. The Division regularly reports scientific progress and program accomplishments to the scientific community, the Institute, Congress, and the public.

The Division of Cancer Control and Population Sciences (DCCPS) supports the NCI mission through an integrated program of high quality genetic, epidemiologic, behavioral, social, applied, and surveillance research. DCCPS-supported research aims to understand the causes and distribution of cancer in populations, supports the development and implementation of effective interventions, and monitors and explains cancer trends in all segments of the population. Central to these activities, the process of synthesis and decision making aids in evaluating what has been learned, identifies new priorities and strategies, and translates research discoveries.

The Division of Cancer Prevention (DCP) manages extramural programs focused on basic prevention science, lifestyle and cancer, cancer biomarkers, chemopreventive agent development, community oncology and prevention trials, early detection, and nutrition science. The Division manages large clinical trials for the prevention and early detection of specific types of cancer. Organ system research focuses on groups of common cancers — e.g., breast and gynecologic cancers, gastrointestinal cancers, lung and upper aerodigestive cancers, and prostate and urologic cancers — for which better prevention and early detection approaches are needed.

The Division of Cancer Treatment and Diagnosis (DCTD) works to identify and exploit the most promising areas of science and technology and to initiate, enable, and conduct research to identify and develop better diagnostic and therapeutic cancer interventions. Division programs focus on cancer diagnosis, imaging, therapy evaluation, developmental therapeutics, radiation, and biometrics. DCTD manages an extensive clinical trials program covering a broad range of cancers and age groups, oversees large initiatives to support drug development and cancer imaging, and supports studies on the special needs of patients with AIDS-related malignancies.

NCI Intramural Program

About 16 percent of NCI research dollars stay at NIH in Maryland, to support the work of intramural scientists in NCI's Center for Cancer Research (CCR) and Division of Cancer Epidemiology and Genetics (DCEG). These intramural investigators focus on basic laboratory investigation and long-term epidemiologic and genetics studies and their rapid translation to intervention development and clinical testing. Patients benefit from access to the research protocols and treatment available at the NIH Clinical Center facility.

A world leader in developing lifesaving treatments for cancer and home to many of the major breakthroughs in cancer research and care, the CCR is at the forefront of cancer scientific investigation. CCR scientists and clinicians are finding better ways to diagnose, prevent, and treat cancer and related illnesses. They work together to help translate new scientific discoveries into state-of-the-art diagnostic tools and therapies for cancer patients. Intramural investigators work in a highly interactive, interdisciplinary environment that maximizes the use of researcher expertise and technology to perform cutting-edge basic, translational, and clinical investigations and facilitate quick response to promising research findings.

DCEG intramural scientists conduct population and multidisciplinary research to discover the genetic and environmental determinants of cancer and new approaches to cancer prevention. The Division conducts broad based, high quality, high impact research through its programs in cancer epidemiology, genetics, statistics, and related areas. DCEG maintains a national and international perspective and gives priority to emergent issues identified through clinical-laboratory, and epidemiologic observations as well as public health concerns. Major areas of investigation include lifestyle and nutritional factors, environmental

and occupational exposures, genetic susceptibility and gene-environment interactions, pharmacoepidemiology, infectious agents, radiation exposure, and methodologic research. With a steady presence on the NIH campus, DCEG is uniquely able to conduct epidemiology research projects that are high-risk or need long-term commitments of funding and scientific staff. The Division conducts and coordinates epidemiologic and interdisciplinary research that responds quickly to emerging public health or scientific issues that might go unattended by other groups without a national or international reach. DCEG scientists and staff develop critical resources, infrastructures, and strategic partnerships in molecular epidemiology as well as fellowship programs that train the next generation of scientists in cancer epidemiology and related fields.

HIV/AIDS–Related Research at NCI

Working through a new Office of AIDS Malignancy, NCI continues its commitment to meeting the needs of people infected with HIV and AIDS who are often more susceptible to some types of cancer. The NCI Intramural Research Program is an internationally recognized center for research in HIV and AIDS, integrating studies across multiple areas including epidemiology, correlative science, and treatment research. Some intramural scientists assess changes in the cancer burden among HIV/AIDS patients whose lives have been extended as a result of improved treatments. Others focus on the development of novel targeted treatments, prevention interventions, and drug resistance for cancers in HIV infected individuals. Still others work to combine their expertise in cancer with that of retroviral vaccines to promote cross fertilization and progress in both areas. The NCI Extramural Research Program supports vital investigator driven HIV/AIDS research as well as the AIDS Malignancy Consortium (AMC), the only clinical trials group aimed at improving the treatment and prevention of cancer in the context of HIV infection. The AMC works closely with National Institute of Allergies and Infectious Disease (NIAID) to manage AIDS associated co-morbidities. We co-fund the Center for AIDS research with NIAID, support collaborative initiatives that leverage other NIH studies, and supply tissue resources for use in HIV/AIDS studies. NCI is also partnering with others on international initiatives including the dissemination of information on AIDS associated malignancies.

Cancer Centers and Centers of Excellence

The NCI Cancer Centers Program supports major academic and research institutions throughout the United States to sustain broad based, coordinated, interdisciplinary programs in cancer research. These institutions are characterized by scientific excellence and capability to integrate a diversity of research approaches to focus on the problem of cancer. The Centers organize and integrate multidisciplinary research across departments and schools within a single institution or within consortia of institutions. Cancer Centers provide scientists with the most advanced technologies and promote new research opportunities, work collaboratively with industry, perform state-of-the-art translational research, and conduct education, outreach, and information programs. Several are highly effective in leveraging their resources for cancer research and education with other organizations in the public as well as private sectors. Of the 60 Cancer Centers supported by NCI, 39 are designated as Comprehensive Cancer Centers because of their coverage of basic, translational, and population research. In addition, Center planning grants are underway at eight institutions that hope to receive NCI Cancer Center designation. NCI is creating new Cancer Center models to extend services to a wider geographic reach within states that do not have the institutional infrastructure to sustain the more traditional NCI-supported Cancer Center. Our proposed new investments to support NCI-designated Cancer Centers are described on page 26.

NCI Centers of Research Excellence also bring together groups of cancer scientists from different areas of expertise. Centers of Excellence are smaller in scale and generally focus on one or a few types of cancer or scientific areas. For example, more than 40 Specialized Programs of Research Excellence (SPOREs) bring together groups of scientists with specialized expertise in translational research for specific cancers. Other examples of NCI Centers of Research Excellence are the Transdisciplinary Tobacco Use Research Centers, In Vivo Cellular and Molecular Imaging Centers, the Centers of Excellence in Cancer Communications Research, and newly established centers for Transdisciplinary Research on Energetics and Cancer and Centers of Cancer Nanotechnology Excellence. Centers of Excellence support interactive, interdisciplinary research, make research resources and flexible exploratory funds available to investigators, and provide research training and career development opportunities.

Networks and Consortia

Networks and consortia are geographically dispersed multidisciplinary groups whose goals require inter-institutional collaborations. They focus on the development and sharing of resources and the development or validation of new interventions ranging from new therapies to genetic risk counseling to outreach. For example, NCI brings investigators together through networks like the Early Detection Research Network, which assembles groups of scientists to identify markers and develop tests to detect early signs of cancer. The Cancer Genetics Network is a nationwide system of research sites located within NCI-designated Cancer Centers that specializes in the study of inherited predispositions to cancer. The Cooperative Human Tissue Network provides investigators with the human tissue specimens that are so critical to cancer research. Six member institutions in this network coordinate the collection and distribution of tissues across the United States and Canada.

NCI's Mouse Models of Human Cancers Consortium provides a vehicle for scientists from around the world to share their expertise and resources in creating strains of mice that develop cancers similar to those seen in humans. The InterLymph Consortium is an open scientific forum for epidemiologic research in non-Hodgkin's lymphoma. NCI's recently formed Consortium of Cohorts addresses the need for large-scale, international collaborations for study of gene-gene and gene-environment interactions in the etiology of cancer. More than 20 cohorts, involving 1.2 million individuals are participating.

With an expected enrollment of 11,000 patients with newly diagnosed lung or colorectal cancer, the Cancer Care Outcomes Research and Surveillance (CanCORS) Consortium project will collect data that reflect the entire span of care from diagnosis through end-of-life care, capturing data from patients, their physicians (surveys and medical records from specialists and non-specialists), and their informal caregivers. Data collected by eight research teams will be used to determine the factors that influence the interventions that cancer patients receive and to evaluate the effects of that care on patient survival, quality of life, and satisfaction with care.

NCI-Supported Clinical Trials

NCI-supported clinical trials have helped to save or extend the lives of millions of people in the United States and around the world. Over 1,500 NCI-supported cancer trials are conducted annually, involving more than 12,000 investigators at the NIH Clinical Center and about 3,000 other sites across the United States. The NCI clinical trials system has been a model for other research institutions. The program is currently working to build a more interactive and coordinated system, one that will be used to prioritize and accelerate the development of new interventions and ensure that those interventions found to be effective are efficiently and seamlessly incorporated into medical practice.

The Clinical Trials Cooperative Group Program promotes clinical trials of new cancer treatments, explores methods of cancer prevention and early detection, and studies quality of life issues and rehabilitation during and after treatment. The Cooperative Group Program involves more than 1,700 institutions that contribute patients to group-conducted trials. Thousands of individual investigators also participate in NCI-supported cooperative group studies. Cooperative groups place more than 22,000 new patients into cancer treatment trials each year. The online Cancer Trials Support Unit (CTSU) Web site centralizes the common administrative, financial, and data collection activities of the cooperative groups. With the CTSU in place, physicians outside NCI's cooperative groups can also enroll patients into NCI-supported clinical trials.

The NCI-supported Community Clinical Oncology Program (CCOP) has also been highly successful in bringing the benefits of clinical research to cancer patients in their own communities. The 61 CCOPs currently supported by NCI, 11 of which are minority-based programs (MCCOPs), involve more than 400 community hospitals in 36 states, Washington, D.C.,

What are the Specific Goals of Cancer Clinical Trials?

Phase I trials are studies involving small numbers of patients to evaluate how new drugs should be given (by mouth, injected into the blood, or injected into the muscle), how often, and at what dose level.

Phase II trials continue to test the safety and efficacy of drugs, usually focusing on how effective they are for specific types of cancer.

Phase III trials test new drugs, new combinations of drugs, or new surgical procedures in comparison to the current standard. Phase III trials generally enroll larger numbers of people and are frequently conducted at multiple locations—e.g., doctors' offices, clinics, and Cancer Centers.

Community-Supported Cancer Trials Make a Difference in the Lives of Many

Several large-scale cancer prevention trials have been made possible through the Community Clinical Oncology Program (CCOP) supported by NCI. Indeed, the first cancer prevention drug, tamoxifen, might never have reached patients without the CCOP network that conducted the Breast Cancer Prevention Trial, on which the approval was based. The trial tested the efficacy of tamoxifen in preventing breast cancer in women at high risk for the disease. Another CCOP trial, the Prostate Cancer Prevention Trial evaluated finasteride as a prostate cancer prevention drug.

The CCOP network remains a strong partner in ongoing studies as well. The Study of Tamoxifen and Raloxifene (STAR) compares raloxifene with tamoxifen in breast cancer prevention. It will continue through 2010. The Selenium and Vitamin E Cancer Prevention Trial (SELECT) is evaluating the supplements to prevent prostate cancer. Results from SELECT should be available in 2013. A perhaps underappreciated component of the CCOP is its support to symptom management trials. These trials may not garner headlines, but their importance in developing interventions to reduce side effects of treatment such as nausea and mucositis is critical.

and Puerto Rico, who participate along with the Cooperative Groups and Cancer Centers in NCI-supported clinical trials. CCOPs make it possible for community oncologists to be involved in clinical research and to provide access for their patients to state-of-the-art cancer care close to home.

NCI is facilitating progress on several new clinical trials initiatives. We are developing a common clinical trials informatics platform that will be overseen by, and made available to, the full range of investigators working within the cancer clinical trials system. This includes NCI clinical faculty, staff, academicians, community physicians, representatives of regulatory agencies and the pharmaceutical industry, research nurses, and patient advocates. We are working with the Food and Drug Administration and the Office of Human Research Protections to develop more effective policies and procedures specific to cancer clinical trials. We are also partnering with the Centers for Medicare and Medicaid Services to develop a systematic process for supporting patients enrolled in cancer diagnostic and therapeutic intervention trials.

Looking to the Future

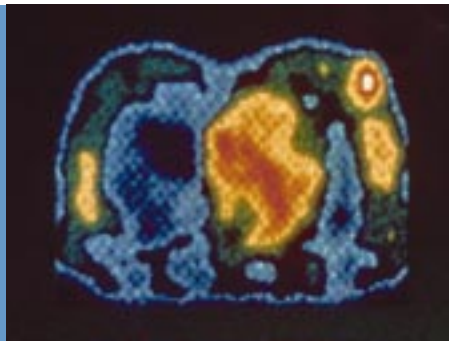
The Clinical Trials Working Group has recently identified 22 recommendations for restructuring the clinical trials enterprise to accommodate advances in molecular medicine. The recommendations include enhancement initiatives that will expand activities already underway and new initiatives that propose fundamental and significant operational changes. Our proposed new investments to implement some of these recommendations in Fiscal Year 2007 are described on page 28.

Technology Development

Identifying many of the complex mechanisms responsible for cancer through genetic and protein microarrays, molecular imaging, and high throughput screening is proving to be pivotal in accelerating our ability to preempt cancer at its various stages. Similarly, technology-dependent, molecularly targeted therapies based on a patient's disease-specific profile of markers provide hope that the cancer burden will be lightened and patients will enjoy a higher quality of life. We are able to make rapid gains against cancer because of the development and availability of advanced technologies that enable accelerated research and create effective interventions.

Bioinformatics

Using the power of modern information technology, NCI is leading the way in developing a bioinformatics platform, cancer Biomedical Informatics Grid (caBIG) that promises to revolutionize the biomedical research enterprise. Scientists in various disciplines will have access to a common infrastructure for collaboration and integration of findings that will make it possible for investigators to accelerate their research. Informatics systems will also assist the cancer community with priority setting, decision making, and participation in order to accelerate the completion of cancer clinical trials. Databases and analytical tools will make information from all clinical trials available to NCI-supported researchers for efficient patient



accrual, information retrieval, and data analysis. Confidential clinical and proprietary information will be protected by controlled, secure access. Advocacy groups and individual patients will be empowered to participate in clinical research, and healthcare providers will become full partners in the research enterprise and educated consumers of research findings.

Cancer Imaging

Advanced imaging technologies are dramatically improving our understanding of cancer biology and facilitating cancer preemption and the clinical management of cancer and cancer risk. Clinicians are increasingly relying on imaging methods as biomarkers for cancer

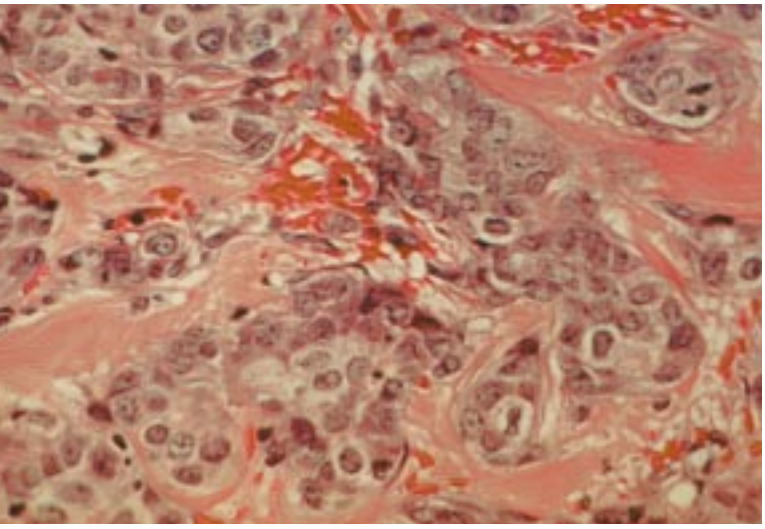
risk and treatment efficacy. Image guided cancer intervention is a rapidly evolving area that may be used to cure some cancers and precancerous lesions, and also to provide minimally invasive, well-tolerated palliative therapies. Imaging informatics optimizes the availability and effectiveness of cancer imaging data in research as well as clinical environments. Imaging methods are used hand-in-hand with emerging technologies such as nanotechnology, proteomics, and high throughput screening to identify cancers earlier and help assess the effectiveness of therapy. Imaging of small animals used in research, particularly genetically engineered mice, is increasingly recognized as a powerful discovery tool in cancer research. As our knowledge of the molecular basis of cancer increases, molecular imaging methods are providing clinicians with telling details about the environs of patients' tissues.

Proteomic Technologies

Scientists are taking new steps to identify profiles, or signatures, of proteins and peptides (fragments of proteins) that are found in tumors and often in the circulating blood that signal early phases of cancer development. Proteins serve complex and diverse functions in the body, from giving structure to our cells to regulating processes such as digestion, respiration, and the growth rate of cells. When proteins do not function properly, normal body processes can go awry. For example, cancer is caused by errors in proteins that regulate when and how fast cells replicate themselves, as well as the timing of cell death. One of the goals in cancer research is to develop technologies that measure these abnormal proteins and can eventually be used as simple diagnostic blood tests. However, there are some sizeable technical challenges that stand in the way of achieving that goal. These abnormal proteins are found in minute quantities in the blood. The net effect is that we need to refine the technology so that it can find "a needle in the haystack" with unprecedented reliability.

NCI is supporting the development of advanced technology platforms for overcoming these barriers and preparing diagnostic methods ready for clinical testing. Mass spectroscopy, a favored approach involving high energy lasers, high powered electronic sensing, and computing, is used to identify specific proteins and their fragments based on their size and electrical

charge. Another avenue is to use DNA and antibodies to capture proteins and measure their quantity on electronic chips. In the near future, patients may have small samples of their blood analyzed using mass spectroscopy and protein chips that will, within minutes, identify abnormal proteins that indicate early, treatable cancers. New infrastructures will help researchers speed development of these technologies and bring them to the clinic. Through a new Mouse Models of Human Cancers Consortium initiative, researchers will create new resources including antibodies, data that provide standards for future measurement comparison, serum specimens, and histologic data. These resources will enable investigators to develop the technology platforms needed to detect proteins at very low levels.



Nanotechnology

Nanotechnology offers an unprecedented and paradigm changing opportunity to study and interact with normal and cancer cells at molecular and cellular scales, in real time and during the earliest stages of the cancer process. Nanotechnology will enhance cancer diagnosis and treatment in numerous ways. Imaging agents and diagnostics will allow clinicians to detect cancer in its earliest, most treatable, presymptomatic stage and provide real time assessments of therapeutic and surgical efficacy for accelerating clinical translation. Multifunctional targeted devices capable of bypassing biological barriers will deliver multiple therapeutic agents at high local concentrations—and with physiologically appropriate timing—directly to cancer cells and tissues that play a critical role in the growth and metastasis of cancer. Nanoscale agents will be capable of monitoring predictive molecular changes and preventing precancerous cells from becoming malignant. Our proposed new investments to support technology development and its linkages to cancer science are described on page 30.

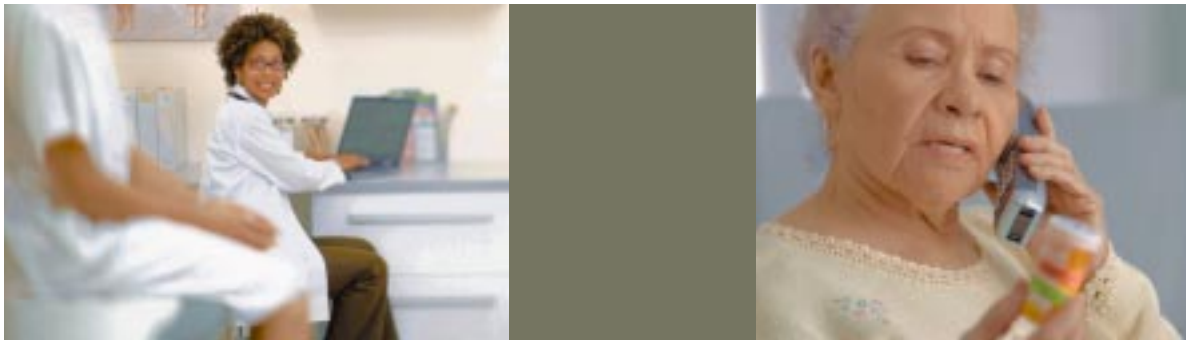
Cancer Surveillance

Cancer researchers depend on comprehensive surveillance data to assess the effectiveness of current cancer interventions, to identify areas of cancer health disparities, and to prioritize areas for further research. NCI's Surveillance, Epidemiology, and End Results (SEER) program serves as the foundation for a national system of data resources on all aspects of cancer surveillance and an authoritative source of information on cancer incidence and survival

in the United States. The SEER program currently collects and publishes cancer incidence and survival data from 14 population-based cancer registries and three supplemental registries covering approximately 26 percent of the U.S. population. Information on more than 3 million *in situ* and invasive cancer cases is included in the SEER database, and approximately 170,000 new cases are added each year. The SEER registries routinely collect data on patient demographics, primary tumor site, morphology, stage at diagnosis, first course of treatment, and follow-up for vital status.

The SEER program supplies researchers with quality data on risk factors, health behaviors, extent of disease, treatment and lifestyle factors, and quality of life for cancer survivors. Scientists use the *Economic Studies in Cancer Prevention, Screening, and Care and Cancer Surveillance Using Health Claims-Based Data Systems*, both generated using SEER data, to assess trends, quality, and the cost of cancer care. Researchers use information generated by SEER Patterns of Care studies to assess the extent and quality of care that cancer patients receive.

The SEER program is the only comprehensive source of population-based information in the United States that includes stage of cancer at the time of diagnosis and survival rates within each stage. The mortality data reported by SEER are provided by the National Center for Health Statistics.



Communication, Education, and Dissemination

Although the delivery of cancer interventions is ultimately the responsibility of healthcare and public health organizations, NCI works to ensure that our research findings reach the community and are translated into practices that help public health professionals, healthcare providers, and patients make better health choices and obtain quality care. NCI proactively disseminates information on research findings, opportunities to

participate in clinical trials, and new interventions through a range of cancer communications activities that supplement the efforts of medical journals and news media. For example, NCI provides Web-based information on cancer and clinical trials, toll-free telephone cancer information service in all regions of the country, and printed brochures and educational packages distributed directly to consumers and through physicians and advocacy organizations.

NCI-supported researchers continuously work to improve methods for reaching all who need to learn about cancer with critical information.

- Public surveys help assess reactions to media coverage about cancer and aid us in communication planning and evaluation, especially in evaluating the public's reaction to controversial coverage.
- Training workshops and toolkits for journalists enhance the quality and quantity of media coverage about cancer science.
- Applied communications studies identify how to best integrate electronic and interpersonal communication systems to improve decision making and facilitate positive changes in health behavior.
- Basic communication research partnerships accelerate discoveries about how cancer information is processed and used.
- The New Media Collaborative focuses on developing tailored communications strategies to benefit specific populations, including medically underserved communities.
- A collaboration between the U.S. Department of Health and Human Services and the Department of Agriculture has been responsible for furthering dissemination of the 5-to-9 A Day message promoting the consumption of fruits and vegetables to diverse populations.
- Research on doctor-patient communications provides practical strategies for dialogue and examines the use of mediated communications to help patients cope with cancer. These efforts include a special focus on minority and underserved patients.

Training and Career Development

Rapid developments in the frontiers of science and technology, including molecular biology and translational medicine, have broadened the scope of cancer research and have presented new challenges for training future cancer researchers in diverse disciplines. NCI devotes

approximately four percent of its annual budget and multiple strategies to preparing the next generation of cancer researchers for challenges that are increasingly multidisciplinary and span basic, clinical, behavioral, and applied research. Each year, we provide cancer research training and career development opportunities to more than 2,000 graduate students, postdoctoral fellows, and oncologists. Some of this training takes place on the NIH campus, but most occurs in universities and teaching hospitals around the United States.

All sponsored traineeships are intended to increase the number of scientists who specialize in the basic or clinical biomedical research fields. We invest in training to support the use of advanced technologies and provide career opportunities to equip scientists to address cancer in underserved populations. We foster development of interdisciplinary teams of scientists to carry out critical translational research. These investments will ensure a steady flow of well trained investigators to focus on the problem of cancer.

NCI Advisory Groups

Scientists, medical experts, and advocates work together to help shape NCI's policies and programs through a number of standing and ad hoc advisory groups. Advisory groups provide seasoned assessment of progress and problems in the Nation's effort to reduce the burden of cancer.

> The National Cancer Advisory Board provides overall guidance for NCI and a final assessment of the research proposals selected for funding through peer review.

> The Board of Scientific Counselors evaluates the progress, performance, and productivity of the Institute's intramural research programs and scientists through regular site visits to NCI.

> The Board of Scientific Advisors plays a similar role for NCI's extramural program, reviewing the progress of ongoing programs and providing feedback on proposed new research activities.

> NCI is strongly influenced by the President's Cancer Panel, which monitors the development and execution of the activities of the National Cancer Program and reports directly to the President.

> The Director's Consumer Liaison Group is an all-consumer advisory committee that provides advice not only to the Director but to a number of specific program areas such as cancer communications, survivorship, and science planning.

> Progress Review Groups of scientific and medical experts and advocates examine the research needs and opportunities for specific types of cancer.

Other Partnerships

Partnerships, traditional and beyond, are vitally important to eliminate bottlenecks, leverage resources, take advantage of expertise outside of the Institute, and build synergy. NCI is increasingly looking beyond its institutional boundaries to engage in various kinds of collaborative efforts.

> The Consortium of Cohorts is an international collaboration of investigators responsible for independently funded population studies involving over a million people. By pooling their data, these scientists have adequate samples sizes to conduct numerous studies leading to valuable insights for cancer prevention and control.

> The Leukemia/Lymphoma Molecular Profiling Project includes a consortium of NCI intramural and extramural investigators who have pooled resources and talent to create a framework for the molecular classification of lymphomas. The large number of samples, substantially more than any single institution could have acquired, has allowed researchers studying diffuse large B-cell lymphoma to draw reliable conclusions about how best to diagnose and treat patients based on the molecular subtype of their disease.

> Through an interagency agreement, NCI and the FDA collaborate to share knowledge and resources to facilitate the development of new cancer drugs and speed their delivery to patients. NCI is also partnering with the Centers for Medicare and Medicaid Services to develop a systematic process for evaluating new diagnostics and therapeutics to aid in payment and coverage decision making.

> *The Annual Report to the Nation on the Status of Cancer* is a collaborative effort involving NCI, the Centers for Disease Control and Prevention (CDC), the American Cancer Society, and the North American Association of Central Cancer Registries.

> In 1999, NCI and the pharmaceutical company Genentech entered into a Cooperative Research and Development Agreement to test treatment of renal cell carcinoma (RCC) patients with the monoclonal antibody Avastin™ (bevacizumab). Based in part on this research, Avastin was approved by the FDA in 2004 for treatment of RCC patients, in combination with the standard chemotherapeutic drug ironotecan, 5-fluorouracil, and leucovorin (ILF). Avastin also looks promising for treatment of breast, colorectal, and other cancers.

- NCI recently established a partnership with pharmaceutical companies Aventis, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, and Novartis to provide funding to Cancer Centers for the design and implementation of new approaches to increasing the participation of newly diagnosed cancer patients in early stage clinical trials.
- The Avon-NCI Progress for Patients Awards Program funds clinical investigation important to breast cancer prevention, early detection, diagnosis, prediction, prognosis, and treatment.
- NCI's Academic Public Private Partnership Program (AP4) is supporting a new paradigm in the discovery of new agents and the development of cancer drugs, and their rapid translation to human clinical trials. Through this program, NCI fosters collaborations among universities, pharmaceutical companies, biotech companies, and nonprofit organizations.
- NCI has partnered with CDC, the Substance Abuse and Mental Health Services Administration, the American Cancer Society, and the Agency for Healthcare Research and Quality to provide evidence-based tools to help states and communities plan, implement, and evaluate evidence-based comprehensive cancer control programs. The Web-based tools are available through the Cancer Control PLANET (Plan Link Act Network) portal located at cancercontrolplanet.cancer.gov.

The Advocate Role in Cancer Research

Cancer advocates may be cancer survivors, family members or life partners, or people involved in cancer-related activities, such as support group leaders or hotline workers. They come from diverse age groups, races, ethnicities, educational levels, and geographic locations. Cancer advocates are intimately familiar with the hopes, struggles, joys, losses, and successes of cancer patients, those at risk for cancer, and their loved ones. Their advocacy helps present the human face of cancer to scientists, administrators, and the general public, reminding us of the "why" in cancer research.

NCI draws upon the expertise of cancer advocates through two major vehicles. The Director's Consumer Liaison Group (DCLG) is made up of 15 cancer advocates, each representing a unique constituency in the advocacy community. DCLG members advise the Director of NCI on a wide variety of issues, programs, and research priorities. NCI also solicits the advice of patients and their family members through the recently created Consumer Advocates in Research and Related Activities (CARRA) program. Through this program, approximately 200 individuals serve as resources to participate in a wide range of NCI activities. For example, they sit on advisory boards of basic and clinical researchers to help assess research needs for specific cancers, provide advice on the design of clinical trials, and review educational materials.

Cancer Research Fosters Medical Advances for Other Diseases

With the stewardship of our resources in recent years, NCI is fostering numerous efforts with results important not just for cancer but for a number of diseases. The early detection work in proteomics conducted through a partnership with FDA is potentially applicable to most acute and chronic diseases. The Cancer Genome Anatomy Project contributed extensively to accelerating the national effort to map the human genome. New high-resolution molecular imaging methods promise to lead to new approaches to the early detection, screening, diagnosis, and image-guided treatment of cancer and other diseases. Infrastructures for therapeutics development such as the Rapid Access to Intervention Development program are being applied to foster new treatments for type 1 diabetes. Apoptosis (programmed cell death) has been heavily researched for cancer but also has implications for neurobiology, immunology, aging, and human development and strong association with autoimmunity and degenerative diseases and conditions. Angiogenesis research is informing the treatment of cancer and the complications of diabetes. In addition, cancer research has shown that the extracellular matrix is associated with cell death, influences angiogenesis, impacts blood vessels and nerves in aging tissues of the musculoskeletal system and skin, and may be important to our understanding of the vascular and neurological changes that accompany aging. The results of studies on tobacco addiction and cessation have implications for the control of heart and lung disease, stroke, and other serious illnesses. As discoveries about the bioactive components arise from NCI nutrition studies, it will be possible to develop more personalized approaches to disease prevention. Multi-agency collaborative research on diet, physical activity, and weight control is identifying societal and environmental approaches that will make it easier for people to make healthy dietary and physical activity choices. Such choices will improve prognosis for overall health and reduce the occurrence of many chronic diseases. In addition, the cancer Biomedical Informatics Grid promises to serve our vital need to develop medical and health information systems that will serve people all across our Nation.

Each of the five new investment areas described on the following pages represents a critical path for reaching NCI's Challenge Goal to the Nation. Each promises to yield high return but will require a substantial investment of resources.

Fostering more integration within and among NCI-designated Cancer Centers will boost synergism, reduce redundancy, and leverage resources. A more extensive, robust, and active Cancer Center system will foster community-based research and service programs targeted to medically underserved populations.

Reengineering our clinical trials system will allow us to move the growing backlog of potential prevention and therapeutic agents through clinical testing. New strategies for improving trial accrual, prioritization, coordination, and efficiency will dramatically accelerate the movement of new interventions into medical practice.

Building better linkages between emerging technologies and cancer science will reduce the cost, improve precision, and reduce harmful side effects of medical procedures. Advanced imaging, clinical proteomics, and nanotechnology will improve our understanding of cancer biology, facilitate the management of cancer risk, and help make "personalized" medicine a reality.

Common platforms and tools for medical informatics and health information systems will be used to support national efforts to develop and use electronic medical and personal health records. The cancer Bioinformatics Grid™ and the cancer clinical trials system provide ideal test beds for development of electronic health systems.

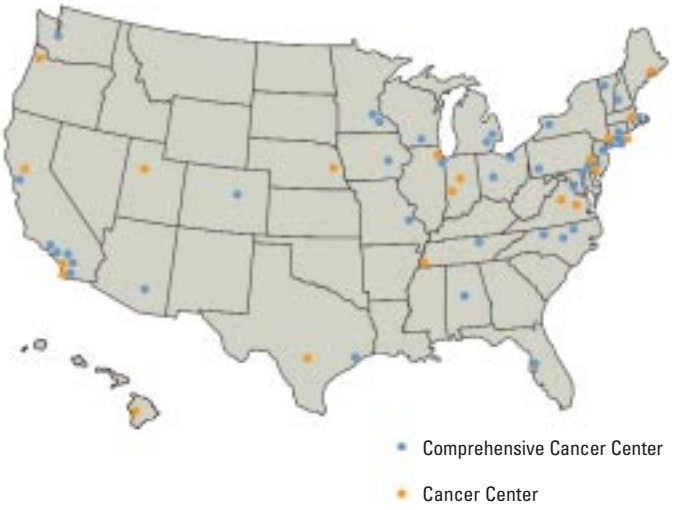
A more integrative approach to understanding cancer will help researchers identify biomarkers for predicting who is at high risk for cancer; identify molecular targets of prevention, diagnosis, and treatment; develop strategies for intervening early in the cancer process; and improve the quality of cancer services.

New Strategic Investments in Fiscal Year 2007

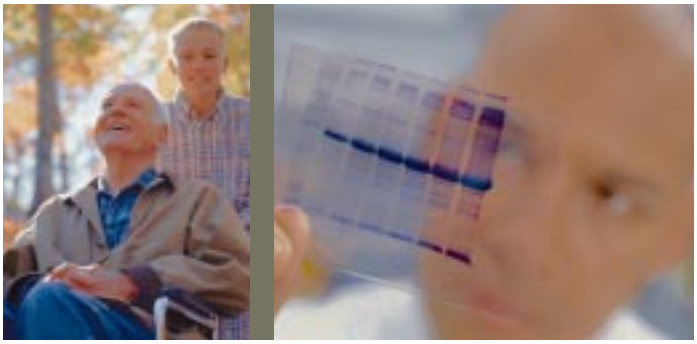
Cancer Centers are vital scientific and geographic hubs of progress for basic discovery. They are central platforms for development of effective approaches to prevention, diagnosis, and therapy. They provide life saving interventions and other advances to patients, their families, and the public. The research endeavors of Cancer Centers contribute new knowledge, improved treatments, and other advances to lower the incidence of cancer and improve survival rates. Increased investment is required to expand the geographic coverage and impact of Cancer Center services.

The NCI Cancer Centers — Driving Progress toward 2015

NCI-designated Cancer Centers extend their reach into the community through networks that link Centers, community hospitals, and private oncology practices to provide patients with state-of-the-art care and access to clinical trials. They bring together the best of basic, translational, and population research to achieve improved cancer prevention, diagnosis, and treatment. Translational research networks link basic research-oriented Centers with the Comprehensive Cancer Centers. Centers also link to their communities and regions through education and outreach networks, provide a locus for stable and integrated consortia and other partnerships, and are an important element of state cancer planning processes nationwide. Cancer Centers are also expected to be at the forefront of cancer prevention intervention development and the dissemination of these approaches to their communities and regions.



The NCI-designated Cancer Centers are vital parts of a national strategy to reduce the suffering and death due to cancer. They are encouraged to stimulate collaborative research involving more than one field of study. Of the 60 Cancer Centers now supported by NCI, 39 are Comprehensive Cancer Centers. These Centers conduct research and provide services directly to cancer patients. These facilities must demonstrate expertise in each of three areas: laboratory, clinical, and behavioral and population-based research. In addition, eight institutions around the country currently hold Center planning grants and hope to receive NCI Cancer Center designation in the near future.



Required Resources

An annual increase of **$164 million** for five years will expand the NCI-designated Cancer Centers program from 60 centers to 75 and achieve a more extensive, robust, and active program through enhanced integration and outreach.

Proposed New Investments

As much as NCI Cancer Centers have contributed to progress against cancer, NCI will enhance their impact even further by expanding the number of Centers, facilitating stronger interaction among them, and fostering fuller outreach efforts into the community.

> Expansion

By adding up to 15 new Cancer Centers over the next five years—increasing the number of Centers from 60 to as many as 75—it will be possible to establish Centers in states and in metropolitan areas where none currently exist. This expanded infrastructure will improve the access of minority and underserved populations to their state-of-the-art cancer care services and research, including community-based research.

> Integration

Horizontal integration will be achieved by implementing progressive bioinformatics, communication, and related systems that will boost synergy, reduce redundancy, and leverage resources across the network of Cancer Centers. NCI will broaden the geographic impact of the Centers, networks, and consortia and vertically integrate them with community and regional health care delivery systems. Vertical integration will provide new avenues of scientific pursuit within Cancer Centers and strengthen outreach to and involvement with the communities they serve. NCI will fund additive programs in collaborative multidisciplinary research and require integration and sharing of results.

> Outreach

New NCI-supported outreach programs will enable Cancer Centers to create and strengthen partnerships with government agencies and community organizations. Centers will also be able to provide expertise and other support to caregivers, patients and families, and appropriate health agencies to a greater extent than previously possible. Moreover, with adequate resources and contemporary technologies, specialized services offered by Cancer Centers in the United States could be utilized anywhere in the world.

Each year, NCI provides leadership, resources, and expertise for a clinical trials program that spans the entire spectrum of activity — from the discovery of novel molecules to the evaluation and application of new agents and interventions. NCI is seeking to develop a more robust infrastructure for cancer clinical trials that will strengthen scientific prioritization and coordination and improve the timeliness with which clinical trials are completed. By embracing this restructuring, NCI will ensure that life saving advances, generated by 40 years of research, make a substantive difference in reaching the NCI Challenge Goal.

Reengineering Cancer Clinical Trials

To this end, NCI recently established the Clinical Trials Working Group to advise the National Cancer Advisory Board on the optimal coordination and future progress of the entire range of intramural and extramural clinical research trials. As we look to the future, we recognize the need to anticipate scientific and technological advancements and enhance partnerships that include an interdisciplinary and translational focus. The need to move the growing backlog of potential prevention and therapeutic agents through clinical testing places the integration and streamlining of clinical trials on a critical path toward improving the quality of care and quality of life for cancer patients.

Clinical oncology is entering a new age, driven by technology and advances in molecular medicine. NCI and the cancer research community must determine the best way to adapt clinical trials to meet these new opportunities. The enormous potential for more specific cancer treatment, coupled with the complexity of evaluating new, highly specific agents, requires nimble clinical trial designs. Imaging can play a role not only in monitoring treatment but also in identifying patients who are most likely to respond to a particular drug or combination therapy. In addition, imaging will be critical to the pre-clinical screening and validation of new targeted compounds. A revamped clinical trials structure will necessitate comprehensive information sharing and close collaboration among clinical, basic, and translational scientists as well as researchers who are developing modern molecular diagnostic and imaging techniques.

Proposed New Investments

NCI will build a highly interactive and optimally coordinated cancer clinical trials system that prioritizes and accelerates the development of new interventions and ensures that they are incorporated into medical practice. The report of the Clinical Trials Working Group (CTWG), *Restructuring the National Cancer Clinical Trials Enterprise*, included 22 recommendations, which emerged from a series of deliberations that included public comment from stakeholders, academic investigators, oncologists, and representatives from government, industry, and professional groups. New investments in Fiscal Year 2007 will be used to implement the recommendations by improving clinical trials coordination, prioritization, standardization, and operational efficiency.

Required Resources

The Clinical Trials Working Group report includes an implementation plan with a timeline and budget for each initiative and recommends that a formal evaluation system be developed to assess the success of the restructuring effort over time. We anticipate the need for an annual increase of **$171 million** over current base NCI levels for five years to deploy a modern integrated cancer clinical trials infrastructure.

> Coordination

NCI initiatives will facilitate cooperation among the functionally diverse components of the current system, including industry and Federal regulatory agencies. Activities will include expanding the NCI clinical trials database review capacity, adjusting grant data reporting requirements, and modifying NCI award guidelines to reward collaboration. NCI will institute new forms of recognition, interact with medical school deans on academic incentives, and build an awareness campaign for an expedited review process with the Food and Drug Administration (FDA). We will also establish a process for aligning NCI with the Centers for Medicare and Medicaid Services to select those studies that are appropriate for reimbursement.

> Prioritization

NCI will improve scientific quality by developing an open and transparent process for the design and prioritization of clinical trials that are both science driven and patient centered. We will establish additional Scientific Steering Committees and convene State-of-the-Science meetings and focus groups that include community oncologists and patient advocates. A budget for correlative science/quality of life studies will be established. The measurement, analysis, and reporting of biomarker data in association with clinical trials will be funded.

> Standardization

To minimize duplication of effort and integrate a national cancer clinical trials network, NCI will support the development of a shared infrastructure of tools and procedures for trial design, data capture, data sharing, and administrative functions. Through the cancer Biomedical Informatics Grid (caBIG), we will create a Web-based tool for clinical trial initiation and concur with industry/FDA on the development of standard Case Report Forms. NCI will hold a conference among investigators from industry and clinical trial sites to standardize clinical trial contract clauses.

> Operational Efficiency

NCI will increase the rate of patient accrual and reduce operational barriers so that trials can be initiated and executed in a timely, cost-effective manner. We will restructure the Phase III trial funding model, begin to increase funding for sites with high accrual rates, complete analysis of institutional barriers to timely trial initiation, and develop approaches to enhance adoption of the NCI Central Institutional Review Board facilitated process.

More than ever before, biomedical science is dependent on the use of advanced technologies to maximize scientific discovery and the delivery of cancer interventions. Working together across communities of scientists and technology experts is a new paradigm for cancer research and development. It increasingly requires new kinds of collaborations and a melding of cultures to achieve an environment friendly to the development, validation, and practical application of promising technologies in cancer discovery, development, and delivery of care.

Building Bridges To Link Science and Technology

Technological advances in bioinformatics, imaging, nanotechnology, genomics, proteomics, metabolomics, and high throughput screening have set the stage for unprecedented progress in our efforts to reduce the burden of disease. Integrating technologies with cancer science promises to improve precision, reduce harmful side effects, and reduce costs of medical procedures. The National Advanced Technology Initiative for Cancer (NATIc) provides the infrastructure for integrating science and technology for the practical development and dissemination of evidenced-based, advanced technology applications to reduce the cancer burden. Through a virtual network of "hubs" and "nodes," innovative, interdisciplinary teams of scientists, mathematicians, engineers, and others will be linked in cutting-edge collaborations for technology development. NCI's cancer Bioinformatics Grid (caBIG) will also be essential to the integration of science and technology. This resource will help optimize data accessibility, widely distribute effective best practices, and conserve resources by preventing duplication of effort.

Proposed New Investments

NCI will provide the leadership to leverage and coordinate NATIc, caBIG, and other resources to optimally integrate technological advances with cancer science. We will cultivate teams of biological scientists, engineers, physicists, and others through innovative funding approaches and by working across public and private settings and with the cancer advocate communities. We will continue to leverage resources and build partnerships with other Federal agencies—including the National Science Foundation, the Department of Energy, the Department of Defense, the National Institute of Standards and Technology, and the National Aeronautics and Space Administration—to integrate a broad spectrum of technological and scientific resources. Partnerships among academic and research institutes, the biotechnology and pharmaceutical industries, and government agencies will accelerate translational application and commercialization of advanced technologies and help bridge the gap between discovery and delivery. We will use new investments in Fiscal Year 2007 to increase our support to science and technology in four critical areas.

Required Resources

New investments in linking advanced imaging, nanotechnology, proteomics and biomarker discovery, and computational modeling into cancer applications will dramatically accelerate our ability to reduce the adverse effects of cancer. We propose a budget increase of **$194.8 million** to continue these efforts in Fiscal Year 2007.

> Cancer Imaging

NCI will support new cancer imaging technologies to enhance understanding of cancer biology and facilitate the preemption and clinical management of cancer and cancer risk. Imaging technologies will be optimized for data sharing; biomarker identification; minimally invasive image-guided prevention, treatment, and palliative therapies; and early detection and assessment of the effectiveness of therapy involving imaging in combination with nanotechnology, proteomics, and high throughput screening.

> Nanotechnology

We will foster the development of nanotechnology interventions to enhance cancer diagnosis and treatment. We will support the development of multifunctional, targeted devices capable of bypassing biological barriers to deliver multiple therapeutic agents at high local concentrations directly to cancer cells and tissues that play a critical role in the growth and metastasis of cancer. We will support research to design and test nanotechnologies to monitor predictive molecular changes and prevent precancerous cells from becoming malignant, manage symptoms of cancer that adversely impact quality of life, predict drug resistance, and enable investigators to quickly identify new drug targets for clinical development.

> Genomics, Proteomics, and Biomarker Discovery

NCI will accelerate the potential of personalized medicine through genomic, proteomic, and other biomarker discovery. Collaboration between cancer scientists and technology experts will accelerate the development of techniques to detect minute quantities of biomarkers susceptibility of precancer, or malignancy in tumor tissue, blood, saliva, or urine. These efforts will lead to more precise prevention interventions, diagnostic testing, prediction of patient response to specific treatments, and use of individualized treatment plans. Advanced preventives, diagnostics, and "designer" therapies will preempt cancer at its earliest stages and deliver minimally invasive and well tolerated individualized care.

> Computational Modeling

NCI will support interdisciplinary collaboration among computer scientists, physicists, and cancer scientists to create multiscale computational models for computerized prediction of outcomes, including patient response to treatment. Computer programs that incorporate complex, interactive calculations will analyze massive amounts of data about cancer cells and their micro- and macroenvironments. Once refined and validated, these models will not only yield insights and knowledge about cancer, but will also provide a tool to improve patient diagnosis and the planning and monitoring of treatment.

NCI is well positioned to support the President's call for Americans to have electronic health records within the next ten years. Several NCI-supported programs are already contributing to the American Health Information Community efforts to promote common standards and interoperability. Medical information systems will provide access to data important for all aspects of cancer research. Electronic patient health records will streamline and personalize cancer clinical trials.

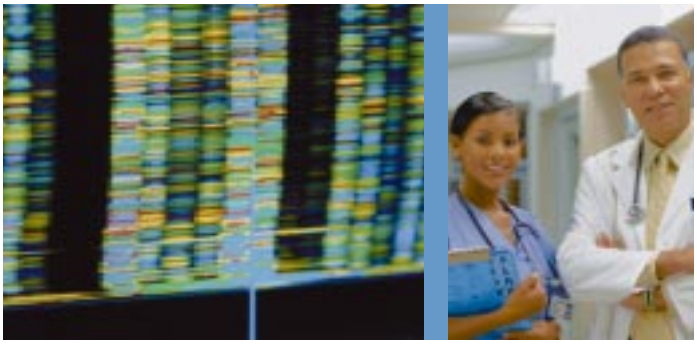
Advancing Medical Informatics

The cancer Bioinformatics Grid™ (caBIG™) is enabling cancer researchers to locate de-identified data on patients with common diagnoses, conditions, or treatments. Investigators use this information to determine patterns of disease, successful treatments, and outcomes that can complete the cycle of science from the bench to the bedside and back to the bench. The NCI Surveillance, Epidemiology, and End Results (SEER) database contains information on more than six million *in situ* and invasive cancer cases with approximately 360,000 new cases accessioned each year. The SEER registries routinely collect data on patient demographics, primary tumor site, morphology, histology, extent of disease, stage at diagnosis, first course of treatment, and follow-up.

Proposed New Investments

With new investments in Fiscal Year 2007, NCI will be able to provide continued technical expertise and models from our experience with cancer to support medical informatics and health information technology for use in both research and medical practice.

NCI is actively integrating a range of diverse services and implementing a business plan for bioinformatics that will further enhance our capabilities in medical informatics and support the national effort in health information systems. Our overall vision is to deliver patient-centric molecular medicine, drawn from richly diverse data sources, in support of improved prevention and treatment. Our enhanced infrastructure will also support cancer patients and their providers in managing the patient's health as cancer increasingly becomes a disease that people live with, rather than die from. We will continue to work closely with the Office of the National Coordinator for Health Information Technology to integrate the national and regional cancer infrastructure into the emerging national health information network and regional health information organizations and to share electronic platforms for use in the broader context.



Required Resources

NCI will need a budget increase of **$80 million** in Fiscal Year 2007 to support the National health information technology efforts and develop cancer-specific applications in medical informatics for use in biomedical research and clinical practice.

> Platforms for Data Exchange

NCI will continue to build upon the caBIG™ foundation for leveraging data, research tools, scientists, and organizations in an open environment with common standards and shared tools. CaBIG™ will be extended to deliver integrated data from diverse sources in support of patient-centric molecular medicine at the point of care. We will build upon the Cancer Research Network and regional networks developed by Cancer Centers to enhance community care.

> Care Delivery and Research Coordination

NCI will support research initiatives and innovations to coordinate care delivery through the integration of electronic medical records systems. As the development of standards for these records and efforts to promote the use of electronic health records have become national priorities, it is important to guide information system developers regarding the needs of clinical care in order to ensure that the records facilitate rather than complicate practice. NCI will support work to help patients, providers, and organizations manage movement of information and coordination of care across the often complex set of providers throughout the course of cancer care. We will also support the national agenda for developing a functional and integrated nationwide electronic health record system.

> Health Care Delivery Systems as Research Resources

NCI will support research to develop innovative approaches to evaluate and improve cancer care delivery through systems interventions that utilize medical informatics and Web-based systems within healthcare delivery. We will draw from advances in electronic medical records—including the patient/provider encounter, pharmaceutical, laboratory and claims information, and use of innovations in Internet systems for healthcare coordination—to improve communication and care coordination between providers and institutions, between patient and providers, and between communities and healthcare delivery institutions. We will work collaboratively with Federal and public partners engaged in improving healthcare delivery systems.

> Medical Informatics Infrastructure

NCI will develop a medical informatics infrastructure to link to national epidemiologic databases and to coordinate communication among the multiple participants in cancer care, including primary care practitioners. The system will make maximum use of NCI investments in cancer communication, statistical modeling, surveillance, cancer treatment, clinical trials, and health systems research and serve as a cancer-led model for the National Health Information Network.

> Enhanced Surveillance Data

NCI will develop software applications to expand and streamline the use of electronic pathology records to include data on insurance, co-morbidities, risk factors, genetic markers, recurrence, and treatment sequelae. Used in combination with existing SEER data, this information will dramatically improve the national capability to monitor and report population level cancer data and establish a model for possible use with other diseases. The effort will lead to increased knowledge of cancer etiology, more accurate cancer prognosis, expanded availability of information on cancer recurrence, and better estimates of the effects of co-morbidities on cancer outcomes for different population groups.

Cancer is a complex disease arising from a myriad of genetic and environmental events that elude and exploit normal cellular processes. The disease process is further confounded by its diversity and its progressive nature. Cancer science is currently at a crossroad where input and approaches from a breadth of disciplines are necessary to understand and appreciate its complexities. Scientists are recognizing the need for study designs with the power to uncover the environmental, lifestyle, genetic, and molecular determinants and pathways involved in cancer initiation, promotion, and progression.

Integrating Cancer Science

Cancer research of the future will be energized as people from the various disciplines combine forces. New paradigms of collaboration will mean new ways of thinking about how we do science. This new culture will require the creation of an environment conducive to change, the merging of old disciplines, and the development of new ones. New funding mechanisms will accelerate development of infrastructures for cutting-edge interdisciplinary research at the intersection of basic, clinical, and population sciences. Integrated review of grant applications will take into account the melding of various disciplines, support large-scale team-based consortia to foster the inclusion of genomics and other emerging technologies into epidemiologic study designs, and use other less formal ways to encourage interdisciplinary teams to evolve in both directed and serendipitous ways.

Investments in integrative science will uncover the many factors influencing cancer initiation, promotion, and progression and thereby hasten the development of cancer prevention, detection, and treatment interventions. Epidemiologists, geneticists, behavioral scientists, and biologists will be working alongside statisticians, engineers, physicists, bioinformaticians and computer scientists, sociologists, psychologists, communication specialists, and educators to improve the quality of cancer care, and health outcomes for diverse populations. Large-scale consortial efforts involving population cohorts will systematically evaluate and identify molecular and biochemical biomarkers of susceptibility, gene-environment interactions, causal pathways and intermediate outcomes, and early-stage lesions amenable to early detection and treatment. Disparate perspectives and approaches will build the kind of synergy required to facilitate the easy flow of information from basic research to application.

Proposed New Investments

NCI will support a broad set of interactions and efforts, both within NCI and across the scientific community, to develop an integrative approach to cancer research. We will use novel funding approaches, promote new paradigms, and encourage multicenter partnerships that will capitalize on efforts across the entire biomedical research community for the benefit of cancer patients and those who care for them. We will develop training initiatives to introduce new and established investigators to the integrative science paradigm. NCI will use new investments in Fiscal Year 2007 to foster integration in four critical areas.

Required Resources

Implementing new pursuits to promote program integration and interdisciplinary team science will require new funding structures and environments conducive to team science and effective collaboration. We estimate the need for a budget increase of **$190 million** for new investments in this area.

> Systems Approach

NCI will use a systems biology approach to build on the totality of information available about cancer processes. The studies will examine the interrelationships among the immune system, the tumor microenvironment, tumor stem cells and self-renewal genes, cellular response to DNA damage, exogenous and endogenous chemicals, epigenetics, inflammation, and mechanisms of cancer susceptibility and resistance. We will support development of computational models to facilitate the generation of hypotheses and to predict or explain the complex, multilevel interactions that lead to cancer initiation and progression.

> Integration of the Biological with the Population and Public Health Sciences

Equally important to the successful understanding of cancer and the development of interventions to benefit all people will be an integrative epidemiologic framework to address NCI strategic research initiatives in cancer prevention and detection, health disparities, and other areas of biological, clinical, sociological, and public health importance. We will support research that extends beyond molecular epidemiology to consider the roles of behavioral, sociocultural and psychosocial factors in cancer susceptibility, utilization of recommended screening, and treatment outcomes.

> Advanced Technologies to Facilitate Integration

NCI will support the development and availability of advanced technologies for use in integrative cancer research. We will work to ensure that research teams have access to advanced technologies, including informatics and computational resources, to enable the generation, integration, and analysis of vast amounts of biomedical information.

> Translation into Practice

We will use integrative approaches to translate interventions to public health and medical practice. NCI will assess and implement recommendations from the National Cancer Advisory Board Translational Research Working Group which will analyze existing research efforts and identify opportunities for accelerating the delivery of validated interventions to the people who can benefit. We will complete the loop of integrative science by developing approaches to inform basic researchers about lessons learned from the application of emerging interventions in clinical and public health settings.

This budget request consists of two components: (1) the increase required to maintain our present level of operations or "current services" and (2) the increases required for the five new investments described in this document. The 6% current services increase is the amount that will be required to sustain existing NCI programs and provide for some minimal growth. Noncompeting Research Project Grants (RPGs) would be funded at committed levels, the success rate for competing RPGs would be maintained at its current rate, there would be a small growth in the number of Cancer Centers, and most other mechanisms would receive sufficient increases to cover cost of living adjustments based on the Biomedical Research and Development Price Index (BRDPI). This budget level also includes funds to make critically needed capital repairs and improvements at the NCI-Frederick Federally Funded Research and Development Center. Adjusting for the capital repairs and improvements increase and the BRDPI increase of approximately 3%, the growth to NCI within a current services budget is less than 2%. The funds needed for the five investment areas are add-ons to the current services level.

At a Glance*

(dollars in thousands)

Fiscal Year 2006 Estimate	$4,798,511
Current Services Increase	291,403
Subtotal	5,089,914
New Investments	
Expanding Cancer Center Reach	164,000
Reengineering Clinical Trials	171,000
Linking Science and Technology	194,800
Advancing Medical Informatics	80,000
Integrating Cancer Science	190,000
Subtotal	799,800
Total NCI	5,889,714

* Does not include the NCI contribution to the NIH Roadmap.

NCI Budget Request for Fiscal Year 2007

Fiscal Year 2007 National Cancer Institute Professional Judgment Budget Request

(dollars in thousands)	FY 2005 Obligations†	Current Services Request for FY 2007: FY 2006 Estimate[1]	Current Services Increase	**Subtotal Current Services**
Research Grants				
Research Project Grants				
Noncompeting	1,595,056	1,625,758	17,964	**1,643,722**
Administrative Supplements	51,840	54,861	1,756	**56,617**
Competing	444,597	453,405	121,595	**575,000**
Subtotal	2,091,493	2,134,024	141,315	**2,275,339**
SBIR/STTR	97,775	97,800	5,130	**102,930**
Subtotal, RPG	**2,189,268**	**2,231,824**	**146,445**	**2,378,269**
Research Centers & SPOREs	**454,032**	**454,295**	**20,537**	**474,832**
Other Research				
Research Careers	76,652	74,970	2,399	**77,369**
Cancer Education	34,581	32,536	1,041	**33,577**
Cooperative Clinical Research	142,847	141,357	4,523	**145,880**
Biomedical Research Support	–	–	–	–
Minority Biomedical Research Support	3,587	3,853	123	**3,976**
Other	42,903	40,146	1,285	**41,431**
Subtotal–Other Research	**300,570**	**292,862**	**9,372**	**302,234**
Total–Research Grants	**2,943,870**	**2,978,981**	**176,354**	**3,155,335**
National Research Service Awards	67,299	67,360	2,236	**69,596**
Research & Development Contracts	351,056	329,778	10,553	**340,331**
Intramural Research	711,009	707,416	22,637	**730,053**
Research Management & Support	182,323	182,246	5,832	**188,078**
Cancer Prevention & Control	531,250	524,730	16,791	**541,521**
Construction (Capital Improvements)	–	–	30,000	**30,000**
Buildings & Facilities	7,936	8,000	27,000	**35,000**
Subtotal, NCI	**4,794,743**	**4,798,511**	**291,403**	**5,089,914**
NCI's Roadmap Contribution‡	**30,500**	**43,263**		**60,000**
Total, NCI	**4,825,243**	**4,841,774**		**5,149,914**

† For comparability, $8.6M was moved from Other to RMS due to change in FY 06 funding of SREA awards.

‡ Roadmap estimate for FY 2007.

[1] FY 2006 Estimate reflects adjustments to the FY 2006 President's Budget.

Research Project Grants
RPGs are the primary funding mechanisms for extramural research and comprise the largest part of the NCI budget. We provide about 5,000 RPGs each year to nearly 600 institutions across the United States at an average cost of $400,000 per grant.

SBIR/STTR
Small Business Innovation Research (SBIR) awards support projects that may ultimately have commercial viability. The government-wide Small Business Technology Transfer (STTR) program promotes technology transfer by helping investigators form public/private partnerships.

Research Centers and SPOREs
NCI-designated Cancer Centers serve as hubs for cutting-edge research, quality cancer care, and community outreach. Centers of Excellence like the SPOREs use flexible funding to investigate specific focus areas and move research quickly from the laboratory to the patient.

Other Research
Other funding mechanisms support the education and training of cancer investigators, Clinical Cooperative Research grants for large-scale, multi-institutional clinical trials, and Resource-Related Research Project grants to increase the availability of research resources.

	New Investments in FY 2007							
Expanding Cancer Center Reach	Reengineering Clinical Trials	Linking Science & Technology	Advancing Medical Informatics	Integrating Cancer Science	**Subtotal New Investments**	**FY 2007 Total Request**	**% Inc Over FY 2006 Estimate**
–	–	–	–	–	–	**1,643,722**	
–	–	–	–	–	–	**56,617**	
29,500	24,750	59,400	4,950	82,665	**201,265**	**776,265**	**71.2%**
29,500	24,750	59,400	4,950	82,665	**201,265**	**2,476,604**	**16.1%**
1,000	–	2,475	–	–	**3,475**	**106,405**	
30,500	**24,750**	**61,875**	**4,950**	**82,665**	**204,740**	**2,583,009**	**15.7%**
42,000	**33,600**	**69,300**	**19,800**	**50,935**	**215,635**	**690,467**	**52.0%**
11,000	1,000	–	–	36,630	**48,630**	**125,999**	
6,000	–	–	–	–	**6,000**	**39,577**	
5,000	32,670	–	–	–	**37,670**	**183,550**	
–	–	–	–	–	–	–	
–	–	–	–	–	–	**3,976**	
5,000	–	8,415	–	–	**13,415**	**54,846**	
27,000	**33,670**	**8,415**	**–**	**36,630**	**105,715**	**407,949**	**39.3%**
99,500	**92,020**	**139,590**	**24,750**	**170,230**	**526,090**	**3,681,425**	**23.6%**
3,000	–	–	–	–	**3,000**	**72,596**	**7.8%**
24,500	63,410	46,332	52,200	–	**186,442**	**526,773**	**59.7%**
–	5,940	6,930	–	17,820	**30,690**	**760,743**	**7.5%**
2,000	1,710	1,948	1,250	1,950	**8,858**	**196,936**	**8.1%**
35,000	7,920	–	1,800	–	**44,720**	**586,241**	**11.7%**
–	–	–	–	–	–	**30,000**	**100.0%**
–	–	–	–	–	–	**35,000**	**337.5%**
164,000	**171,000**	**194,800**	**80,000**	**190,000**	**799,800**	**5,889,714**	**22.7%**
						60,000	**38.6%**
						5,949,714	**22.9%**

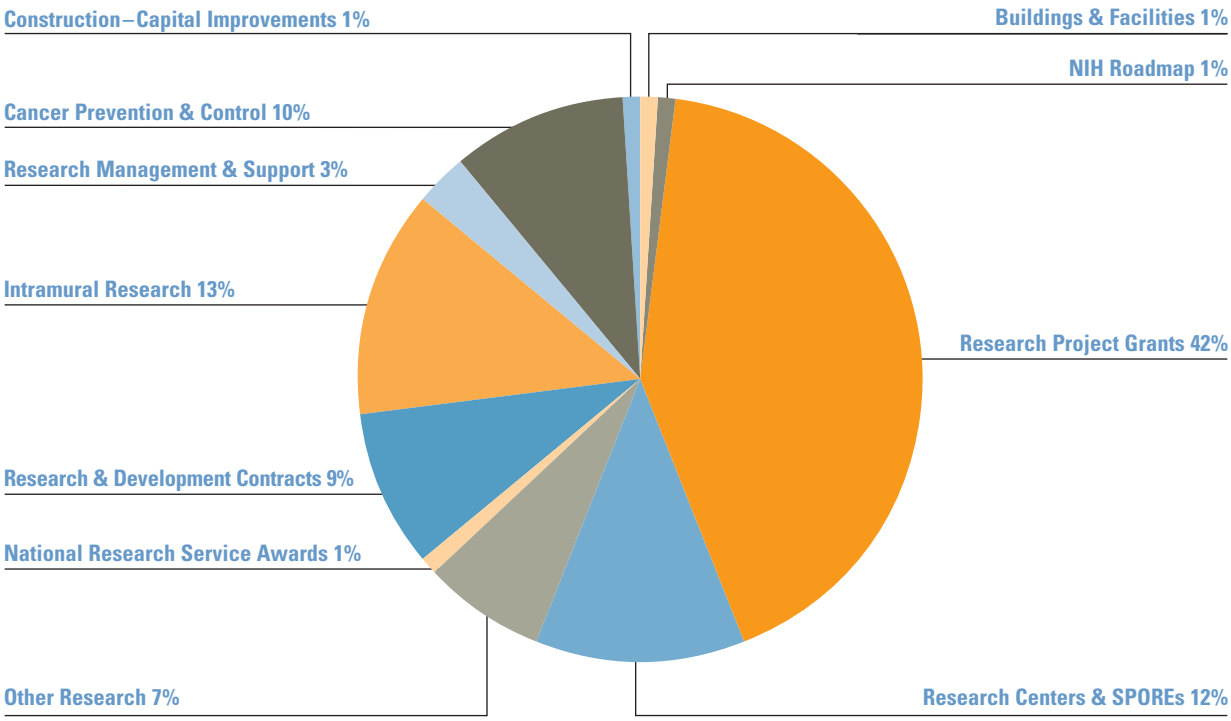
National Research Service Awards
Individual NRSAs enable experienced scientists to enhance and expand their research knowledge and skills. Institutional NRSAs support predoctoral and postdoctoral training at qualified institutions.

Research & Development Contracts
Research and development contracts are used for various NCI research programs including drug development, technology advancement, and epidemiology.

Intramural Research
The NCI intramural research program provides a uniquely interactive, interdisciplinary environment for basic laboratory and long-term epidemiologic and genetics studies and their rapid translation to intervention development and clinical testing.

Research Management & Support
Research management and support funds are used for technical and administrative services including central administration, overall program direction, grant and contract administration, human resources, program coordination, and financial management.

Distribution of Fiscal Year 2007 Budget Request ($5,949,714,000)



Cancer Prevention & Control
Cancer prevention and control funds are used to support research, communication, and other activities to reduce cancer risk, incidence, morbidity, and mortality and improve the quality of life for cancer patients.

Construction (Capital Improvements)
The NCI capital improvements program supports the creation of additional state-of-the-art laboratories and clinics for basic and applied research including biorepositories, imaging, and bioinformatics facilities.

Buildings & Facilities
NCI's building and facilities program supports repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

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Valuable World Wide Web Locations

For Cancer Information

National Cancer Institute **cancer.gov**

NCI Cancer Information Service **cis.nci.nih.gov**

Clinical Trials **www.cancer.gov/clinicaltrials**

Cancer News **newscenter.cancer.gov**

Cancer Science **newscenter.cancer.gov/sciencebehind**

Cancer Progress Report **progressreport.cancer.gov**

Mortality Maps and Graphs **www.cancer.gov/atlasplus**

Surveillance, Epidemiology, and End Results **seer.cancer.gov**

NCI Progress Report **cancer.gov/aboutnci/annualreport**

National Institutes of Health **www.nih.gov**

Department of Health and Human Services **www.hhs.gov**

Planning and Priority Setting at NCI

This Document Online **plan.cancer.gov**

Office of Science Planning and Assessment **planning.cancer.gov**

Disease-Specific Research Agendas **prg.cancer.gov**

Disease-Specific Research Initiatives **cri.cancer.gov**

NCI Research Funding

Funding Opportunities **cancer.gov/researchfunding**

Initiatives by Type of Research **cri.cancer.gov**

Cancer Research Portfolio

NCI Cancer Research Portfolio **researchportfolio.cancer.gov**

International Research Portfolio **www.cancerportfolio.org**

NCI Research Tools

Research Resources **resresources.nci.nih.gov**

Cancer Genome Anatomy Project **cgap.nci.nih.gov**

Center for Bioinformatics **ncicb.nci.nih.gov**

Cancer Imaging Programs **imaging.cancer.gov** and **ccr.cancer.gov/tci/imaging.asp**

Developmental Therapeutics Program **dtp.nci.nih.gov**

Intramural Resources **ccr.cancer.gov/initiatives**

Nanotechnology **nano.cancer.gov**

Office of Technology and Industrial Relations **otir.cancer.gov**

NCI Clinical Trials Programs and Initiatives

Clinical Trials Working Group **integratedtrials.nci.nih.gov/ict/**

Community Clinical Oncology Program **cancer.gov/prevention/ccop**

Cancer Therapy Evaluation Program **ctep.cancer.gov**

Cancer Trials Support Unit **www.ctsu.org**

Centers, Networks, and Consortia

NCI Cancer Centers Program **cancer.gov/cancercenters**

Specialized Programs of Research Excellence **spores.nci.nih.gov**

Early Detection Research Network **cancer.gov/prevention/cbrg/edrn**

Cancer Family Registries **epi.grants.cancer.gov/CFR**

Cancer Genetics Network **epi.grants.cancer.gov/CGN**

Mouse Models of Human Cancers Consortium **emice.nci.nih.gov**

Training and Education

Research Training, Career Development, and Education **cancertraining.nci.nih.gov**

Office of Education and Special Initiatives **cancer.gov/aboutnci/oesi**

Contacting the NCI Information Service

By phone **1-800-4-CANCER** (1-800-422-6237)
[For deaf and hard-of-hearing 1-800-332-8615]
This phone service includes telephone-based assistance for smokers who want to quit.

On the Web **cis.nci.nih.gov**

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By email **cisocc@pop.nci.nih.gov**

By Internet **cancer.gov/publications**

By phone **1-800-4-CANCER**

By fax **301-330-7968**

Each year, as mandated by the National Cancer Act of 1971 (P.L. 92-218), the National Cancer Institute (NCI) prepares a plan for building on research successes, supporting the cancer research workforce with the technologies and resources it needs, and ensuring that research discoveries are applied to improve human health. This annual plan and budget proposal is provided directly to the President of the United States for formulating the budget request to Congress. This document is also used by NCI staff; the researcher community; professional organizations; advisory groups; cancer information, education, and advocacy organizations; and public and private policy makers. It is our hope that this document will inspire all who read it to join the fight against cancer.

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