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Cancer Centers Seek Greater Enrollment in Early Clinical Trials



Overcoming Barriers to Early Phase Clinical Trials

Researchers from National Cancer Institute (NCI)-designated Cancer Centers met in Denver last month to share preliminary findings from seven pilot studies aimed at increasing participation in early phase clinical trials, particularly among elderly and underserved populations.

The meeting was the third workshop organized under the 2003 NCI-led initiative, "Overcoming Barriers to

Early Phase Clinical Trials."

The workshops allow grantees to exchange ideas on why certain groups do not join phase I and II clinical trials and what can be done about it.

"We are looking at a variety of different approaches for overcoming barriers, and it's important to say at this point that the initiative is still a work in progress," said Dr. Edward Trimble of NCI's Division of Cancer Treatment and Diagnosis. Among the strategies being tested are the use of counselors to guide patients through the clinical trials process, community education

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Director's Update

Bringing Health and Hope to Us All

In this issue of the *Bulletin*, we celebrate the NCI Cancer Centers Program and the 60 institutions it currently funds. It's impossible to capture the program's history and spirit in 8 pages and a few thousand words, but I hope you'll come away understanding how important the Cancer Centers are in supporting NCI's mission.

It's been 35 years since the Yarborough Committee—a panel of medical and policy experts convened by the Senate committee chaired by Sen. Ralph W. Yarborough (D-Texas)—recommended that Comprehensive Cancer Centers serve as a focal point to speed progress in a new, coordinated assault on cancer. President Nixon signed the National Cancer Act

1 year later, and many of us have spent untold hours attempting to achieve the noble goal set forth in that law.

The National Cancer Act significantly altered the cancer research landscape. In particular, it changed how NCI interacts with outside research institutions, granting NCI new authorities that, in effect, have built an oncology clinical research infrastructure that supports advanced biomedical technology development and is characterized by scientific excellence.

By 1976, when I began my fellowship in urologic oncology at M.D. Anderson Cancer Center, the law's early impact was already being felt: 19

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(Greater Enrollment continued from page 1)
programs, and equipping oncologists with Personal Digital Assistants (PDAs) so they can identify open trials during office visits with patients.

Early phase clinical trials determine which agents enter the clinical pipeline and are eventually tested in larger studies. Different groups may respond to treatments differently, so broad participation in early trials is critical. For example, the lack of participation among patients over the age of 65—many of whom may take several medications—could pose a public health challenge in the years ahead.

“The population is aging, and we need to do a better job defining the appropriate doses and toxicity of the agents we use to treat cancer,” said Dr. Michele Basche of the University of Colorado Health Services Center. Her team found that logistical barriers, such as transportation, often prevent older patients from joining trials.

The “Overcoming Barriers” initiative was launched 18 months ago as a public-private partnership supported by NCI; the Association of American Cancer Institutes; Friends of Cancer Research; the Foundation for the National Institutes of Health (NIH); and five pharmaceutical companies: Aventis, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, and Novartis.

During the project’s planning stages, NCI-designated Cancer Centers were the obvious choice to carry out the initiative, according to Dr. Linda Weiss, chief of NCI’s Cancer Centers Branch. “The Centers are really a clinical trials powerhouse because they have strong links to local communities and also to drug companies and NCI,” she said.

NCI-designated Cancer Centers provide the majority of patients for

NCI clinical trials, and they “certainly provide a large measure of intellectual leadership in our clinical trials program,” noted Dr. Trimble. “NCI relies heavily on the doctors, nurses, and data managers in our Cancer Centers to help conduct trials.”

The “Overcoming Barriers” initiative is funding projects at Baylor College of Medicine; Ohio State University; Massachusetts General Hospital; Washington University, St. Louis; University of California, Davis Cancer Center; University of Colorado Health Services Center; and University of Pittsburgh Cancer Institute.

The initiative may be extended beyond its originally scheduled end date of August 2005. Final results and recommendations will be reported at major scientific meetings and disseminated through the popular press and scientific literature. ♦

(Director’s Update continued from page 1)
Cancer Centers were designated as “comprehensive,” P30 core grants were established, and the program had a budget of approximately \$47 million. When I arrived at NCI 26 years later, the program had blossomed, with a P30 budget of \$201 million and rising interest in achieving Cancer Center designation among medical research institutions across the country.

Now, after 3 years as NCI director, I’ve had the fortune to visit a number of NCI-designated Cancer Centers and I am always impressed by their talented research personnel and the unequalled services their medical and support staffs provide. Each center is unique, but all push the standard of patient care to a higher level. Some, for example, are offering robotic surgery, a minimally invasive tool that can improve the surgeon’s ability to excise tumors while also reducing

side effects. Others have launched survivorship centers that offer psychosocial and other support services.

I have been particularly impressed with Cancer Centers’ eagerness to work more closely with NCI on initiatives. The cancer Biomedical Informatics Grid (caBIG) is an ideal example. Most of the Cancer Centers are taking part in developing what I believe will be a revolutionary tool in accelerating the pace and efficiency of cancer research. And in May, Cancer Center directors will meet for the second year in a row to discuss with NCI leadership future opportunities and challenges for their centers in the National Cancer Program.

I have also seen how Cancer Centers affect the people and institutions around them. Whether conducting outreach to underserved minority groups, sponsoring educational courses about cancer prevention, or partnering with local biotech companies on cutting-edge research, NCI-designated Cancer Centers represent an important thread in the fabric of our nation’s cancer community.

Each Cancer Center is unique, but they all share one very important attribute: compassionate staff who work diligently toward the goal of transforming this disease from one that debilitates and kills to one that can be identified early and ameliorated. Across the country, in laboratories, hospitals, and public education venues, these people are the hands, the hearts, and the minds that are fulfilling NCI’s mission and bringing health and hope to all of us. My sincerest gratitude to all of our Cancer Center colleagues for the tremendous work you do every day. ♦

Dr. Andrew C. von Eschenbach
Director, National Cancer Institute

NCI-designated Cancer Centers

New England	
■ Yale Cancer Center, CT	http://www.info.med.yale.edu/ycc
▲ The Jackson Laboratory, ME	http://www.jax.org
■ Dana-Farber/Harvard Cancer Center, MA	http://www.dfcc.harvard.edu
▲ MIT Center for Cancer Research, MA	http://web.mit.edu/ccr
■ Norris Cotton Cancer Center, NH	http://www.cancer.dartmouth.edu
■ Vermont Cancer Center, VT	http://www.vermontcancer.org
Mid-Atlantic	
■ Lombardi Comprehensive Cancer Center, DC	http://lombardi.georgetown.edu
■ The Sidney Kimmel Comprehensive Cancer Center, MD	http://www.hopkinskimmelcancercenter.org
■ The Cancer Institute of New Jersey, NJ	http://www.cinj.org
▲ Albert Einstein Cancer Center, NY	http://www.aecom.yu.edu/cancer
■ Roswell Park Cancer Institute, NY	http://www.roswellpark.org
▲ Cold Spring Harbor Laboratory, NY	http://www.cshl.org
▲ NYU Cancer Institute, NY	http://www.med.nyu.edu/nyuci
■ Memorial Sloan-Kettering Cancer Center, NY	http://www.mskcc.org
■ Herbert Irving Comprehensive Cancer Center, NY	http://www.ccc.columbia.edu
■ Abramson Cancer Center, PA	http://www.pennccancer.org
▲ The Wistar Institute, PA	http://www.wistar.org
■ Fox Chase Cancer Center, PA	http://www.fccc.edu
▲ Kimmel Cancer Center, PA	http://www.kcc.tju.edu
■ University of Pittsburgh Cancer Institute, PA	http://www.upci.upmc.edu
South	
■ UAB Comprehensive Cancer Center, AL	http://www3.ccc.uab.edu
■ H. Lee Moffitt Cancer Center & Research Institute, FL	http://www.moffitt.usf.edu
■ UNC Lineberger Comprehensive Cancer Center, NC	http://www.unclineberger.org
■ Duke Comprehensive Cancer Center, NC	http://cancer.duke.edu
■ Wake Forest Comprehensive Cancer Center, NC	http://www.wfubmc.edu/cancer
▲ St. Jude Children's Research Hospital, TN	http://www.stjude.org
■ Vanderbilt-Ingram Cancer Center, TN	http://www.vicc.org
■ M.D. Anderson Cancer Center, TX	http://www.mdanderson.org
▲ San Antonio Cancer Institute, TX	http://saci.uthscsa.edu
▲ UVA Cancer Center, VA	http://www.healthsystem.virginia.edu/internet/cancer
▲ Massey Cancer Center, VA	http://www.vcu.edu/mcc

▲ = Cancer Center ■ = Comprehensive Cancer Center

For the most up-to-date list of NCI-designated Cancer Centers and their contact information, go to <http://www3.cancer.gov/cancercenters/centerslist.html>.

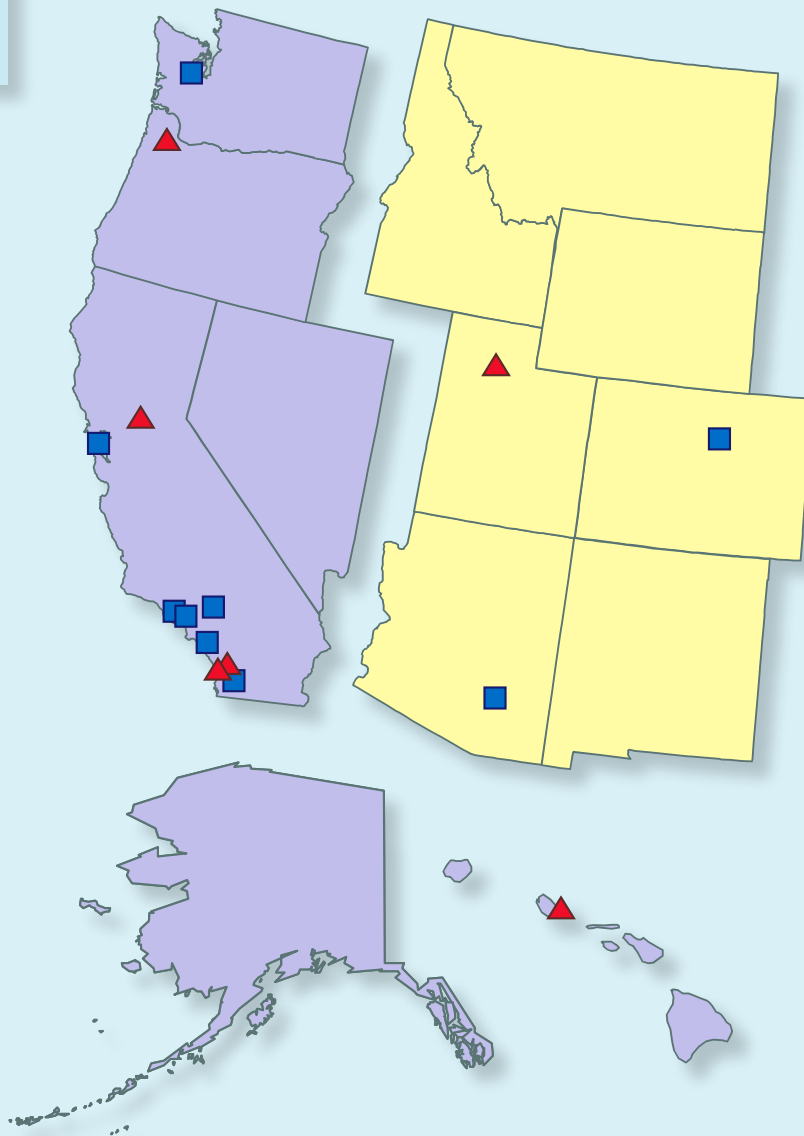
Midwest	
▲ University of Chicago Cancer Research Center, IL	http://www-uccrc.uchicago.edu
■ Robert H. Lurie Comprehensive Cancer Center, IL	http://cancer.northwestern.edu
▲ Indiana University Cancer Center, IN	http://iucc.iu.edu
▲ Purdue University Cancer Center, IN	http://www.cancer.purdue.edu
■ Holden Comprehensive Cancer Center, IA	http://www.uihealthcare.com/depts/cancercenter
■ University of Michigan Comprehensive Cancer Center, MI	http://www.cancer.med.umich.edu
■ The Meyer L. Prentis Comprehensive Cancer Center of Metropolitan Detroit, MI	http://www.meyerprentiscccmd.org
■ University of Minnesota Cancer Center, MN	http://www.cancer.umn.edu
■ Mayo Clinic Cancer Center, MN	http://mayoresearch.mayo.edu/mayo/research/cancercenter
■ Siteman Cancer Center, MO	http://www.siteman.wustl.edu
▲ UNMC Eppley Cancer Center, NE	http://www.unmc.edu/cancercenter
■ Case Comprehensive Cancer Center, OH	http://cancer.case.edu
■ Comprehensive Cancer Center—Arthur G. James Cancer Hospital & Richard J. Solove Research Institute at Ohio State University, OH	http://www.jamesline.com
■ University of Wisconsin Comprehensive Cancer Center, WI	http://www.cancer.wisc.edu
Rocky Mountain	
■ Arizona Cancer Center, AZ	http://www.azcc.arizona.edu
■ University of Colorado Cancer Center, CO	http://www.uccc.info
▲ Huntsman Cancer Institute, UT	http://www.hci.utah.edu
Pacific	
■ City of Hope National Medical Center, CA	http://www.cityofhope.org
▲ Salk Institute, CA	http://www.salk.edu
▲ The Burnham Institute, CA	http://www.burnhaminstitute.org
■ Rebecca and John Moores UCSD Cancer Center, CA	http://cancer.ucsd.edu
■ Jonsson Comprehensive Cancer Center, CA	http://www.cancer.mednet.ucla.edu
■ USC/Norris Comprehensive Cancer Center, CA	http://ccnt.hsc.usc.edu
■ Chao Family Comprehensive Cancer Center, CA	http://www.uclhs.uci.edu/cancer
▲ UC Davis Cancer Center, CA	http://www.ucdmc.ucdavis.edu/cancer
■ UCSF Comprehensive Cancer Center & Cancer Research Institute, CA	http://cc.ucsf.edu
▲ Cancer Research Center of Hawaii, HI	http://www.crch.org
▲ OHSU Cancer Institute, OR	http://www.ohsucancer.com
■ Fred Hutchinson Cancer Research Center, WA	http://www.fhcr.org

NCI-designated Cancer Center Locations

Cancer Centers have significant visibility and prestige in the research community, with increased access to funding from NCI and outside sources. This attracts a higher caliber of clinical and research staff, as well as more patients, to the Cancer Centers.

All eight members of the Cancer Genetics Network are Cancer Centers.

Excluding trials sponsored by the cooperative groups and the pharmaceutical industry, Cancer Centers reported over 2,700 active clinical trials in FY 2003. These trials, which were designed by investigators within the Cancer Centers, include both early and later phase trials that represent translation of basic laboratory findings in the Center, as well as collaborations with the pharmaceutical industry.



▲ **Cancer Center (21)**

■ **Comprehensive Cancer Center (39)**

Cancer Centers have a scientific agenda focused on basic, population, or clinical research, or any two of these three components.

Comprehensive Cancer Centers integrate research activities across all three major areas: basic, clinical, and population research.

NCI based its original model for Cancer Centers on established, free-standing institutions, including Roswell Park, Memorial Sloan-Kettering, M.D. Anderson, and Fox Chase.

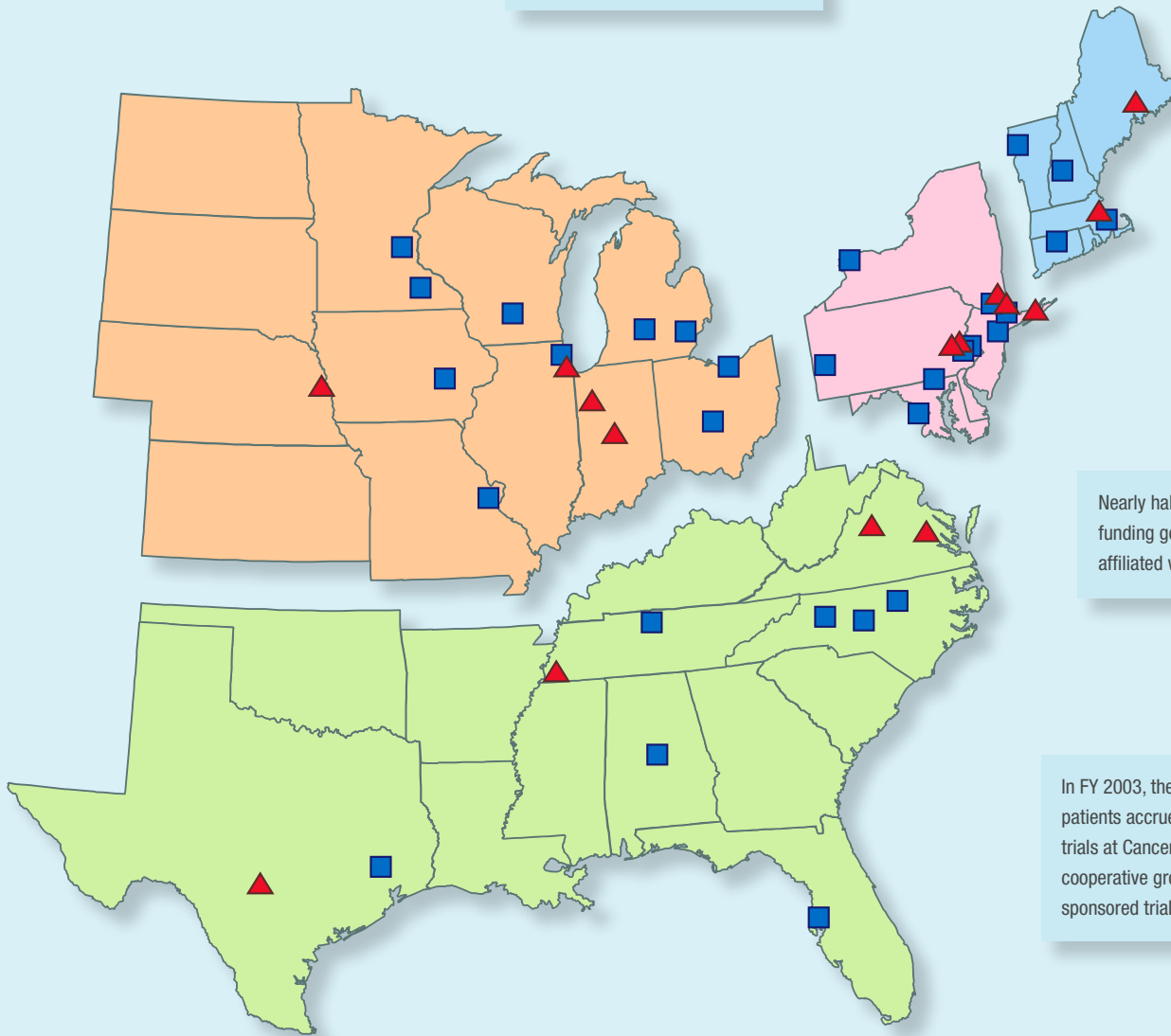
Cancer Center support grants fund 675 shared resources at Cancer Centers, including specialized equipment, facilities, pathology services, tumor procurement, tissue culture, data registries, chemical and drug synthesis labs, and others.

Fifty-five of the 58 NCI Special Programs of Research Excellence (SPoREs) are in Cancer Centers.

Three of four grantees recognized as NCI Centers of Excellence in Communications Research are in Cancer Centers.

More than 50 Cancer Centers are currently piloting caBIG, an informatics infrastructure for sharing tools and data in an open environment with common standards.

The Cancer Centers Program supports infrastructure for 13,666 basic, clinical, prevention, and population science investigators.



Nearly half of NCI's extramural funding goes to investigators affiliated with Cancer Centers.

In FY 2003, the number of patients accrued to all clinical trials at Cancer Centers, including cooperative group and industry-sponsored trials, was 43,650.

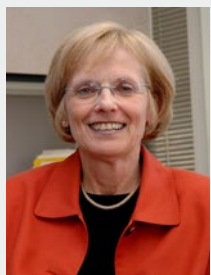
Six of the seven NCI *In Vivo* Cellular and Molecular Imaging Centers are in Cancer Centers.

Nine of 10 members of the NCI Small Animal Imaging Resource Program are in Cancer Centers.

Nearly two-thirds of the research funding that NCI grants through the R01 mechanism goes to investigators affiliated with Cancer Centers.

A Conversation With...Dr. Linda Weiss Chief, NCI's Cancer Centers Branch

What determines the overall number of Cancer Centers funded by NCI?



The original intent of Congress was to have a center within 200 miles of every U.S. resident, enhancing the application of cancer discoveries to patients and people at risk. As a consequence, NCI has never set limits on their number. An applicant must achieve a meritorious priority score in peer review to be funded. Obviously, the NCI budget also has some effect, but we've always supported the funding of outstanding new centers, even in times of budget constraints.

Can any institution that conducts cancer research become an NCI-designated Cancer Center?

In theory, yes, but the requirements are steep: a large cancer-relevant grant funding base; substantial institutional commitment in the form of space, resources, and authorities provided to the Center director; organization of transdisciplinary research across all scientific areas of the institution to "make the whole greater than the sum of its parts;" and, specifically for comprehensive centers, community outreach, education, and training activities. The average NCI grant base for existing centers is somewhere around \$11 million, so that gives you an idea of the critical mass of research required.

What impact do the guidelines issued last year have on Cancer Centers?

The new guidelines were partly a response to recommendations made to NCI by the P30/P50 Ad Hoc Working Group Report, but we also introduced formatting changes and some templates to standardize data submissions. The guidelines just went into effect on February 1 and it'll take several application cycles before we can assess their impact.

How would you summarize the contribution that Cancer Centers make to the overall cancer community?

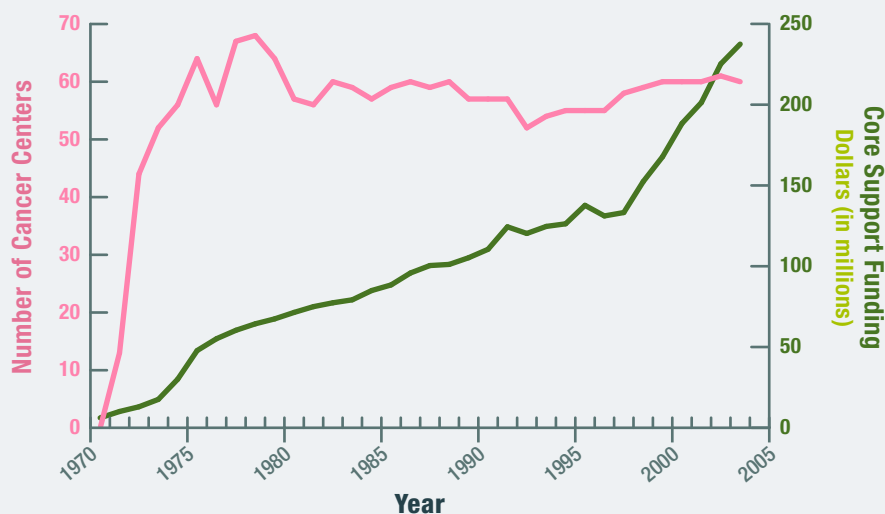
When you combine NCI awards with the number of grants received from other NIH institutes and sponsors, centers have significant resources to leverage against the cancer problem.

They also have an environment that fosters basic discovery and its translation into cancer treatment, prevention, and control activities; and the ability to network both within their community and with each other, so there's extraordinary research power.

While the NCI designation is based solely on an evaluation of the science, centers are also chief deliverers of medical advances to patients and their families, providing state-of-the-art care and access to clinical trials. They serve as the major training ground for new clinicians and researchers and have the strong links with national, state, and local agencies and advocacy groups needed to address the problems in their communities.

Over time, they've been variously described as the "jewels in the NCI crown," and the "ships of the line" and these descriptions are very fitting. Their contributions have been enormous and we see them continuing to escalate in the future. ♦

Growth of the NCI Cancer Centers Program Over Time



Source: NCI Financial Management Branch, <http://www3.cancer.gov/admin/fmb>

History of the NCI Cancer Centers Program

"The National Cancer Institute should closely study the use of cancer research centers for it is here that many impressive research findings are being and will be uncovered. It is also here that the effectiveness of these findings can be proved."

—The National Cancer Act of 1971 (P.L. 92-218)

1960

1961—NIH establishes the Clinical Research Facilities Grant to construct new facilities designed exclusively for cancer research.

1963—The first cancer center core grant is awarded to the Institute for Cancer Research (now part of Fox Chase Cancer Center). NCI funds a total of 12 Cancer Centers.

1968—The House Appropriations Committee suggests that geographic distribution should be considered in establishing Cancer Centers.

1971—President Nixon signs the National Cancer Act, authorizing \$1.5 billion for a National Cancer Program and the establishment of 15 new NCI-designated Cancer Centers.



1985—The Health Research Extension Act removes annual limitations on funding for NCI-designated Cancer Centers and extends the support period from 3 years to 5 years.

1990—New guidelines are issued defining the concept and eight criteria for NCI-designated Comprehensive Cancer Centers.

1992—NCI-designated Cancer Centers become "institutional," integrating research programs across organizational boundaries and consolidating multiple NCI support grants into one center grant.

2003—The Report of the Ad Hoc P30/P50 Working Group of the NCAB is released, with recommendations for positioning Center and SPORE award mechanisms to support new opportunities in research discovery, development, and delivery.

1960—NCI begins providing grants to cancer-focused interdisciplinary centers that had already been created with state or private funds, upon the recommendation of the NIH Task Force on Categorical Research Centers.



1973—Eight NCI-designated Cancer Centers are recognized as "comprehensive," according to criteria established by the National Cancer Advisory Board (NCAB).

1975—The Senate endorses the establishment of 30 to 35 NCI-designated Comprehensive Cancer Centers to permit an estimated 80 percent of the U.S. population access within a reasonable driving distance.

1978—National Cancer Act reauthorization urges the centers to engage in public information programs.

1989—At the request of Congress, the Institute of Medicine conducts an evaluation of the Cancer Centers Program and makes recommendations for increased funding, organizational relocation, and new program directions.

1991—The first request for applications is issued for the P20 Planning Grant Program to develop Cancer Centers of Excellence in underdeveloped areas of the country. Twelve are ultimately funded in the first round of applications.

1996—The final report of the Cancer Centers Program Review Group is released, with recommendations for changes in review and program administration.

2004—An NCI-designated Cancer Center Directors Retreat is held in Bethesda, Md., with dialogue between NCI leadership and the Cancer Center directors on goals, strategies for their accomplishment, and new guidelines based on the Working Group Report.

2005

Cancer Center Web Sites: Another Way to Locate Clinical Trials

Patients and clinicians who are searching for clinical trials can use several resources, including NCI's PDQ database (<http://cancer.gov/search/clinicaltrials>) and Cancer Information Service (1-800-4-CANCER), as well as the NIH's ClinicalTrials.gov database (<http://www.clinicaltrials.gov>), which is managed by the National Library of Medicine.

Another way to search for clinical trials—one that may be more practical, in some cases—is by searching the NCI-designated Cancer Centers' Web sites directly.

More about locating clinical trials at NCI-designated Cancer Centers can be found at: <http://cancer.gov/clinicaltrials/finding/NCI-cancer-centers/map>. Patients or family members should note that the summaries describing these opportunities may be written in technical language and should be shared with a health care provider before making a decision about enrollment in a trial. ♦

Bevacizumab Prolongs Survival for Some Patients with Advanced Lung Cancer

Preliminary results from a large, randomized, NCI-sponsored clinical trial for patients with previously untreated advanced non-squamous, non-small cell lung cancer show that those who received bevacizumab (Avastin) with standard chemotherapy lived longer (median survival 12.5 months) than patients who received the same chemotherapy without bevacizumab (median survival 10.2 months). This difference is statistically significant. More information can be found at <http://cancer.gov/newscenter/pressreleases/AvastinLung>. ♦



Community Update

Cancer Patient Education Network Set to Expand Mission

NCI founded the Cancer Patient Education Network (CPEN) in 1989 as an informal network of patient educators at NCI-designated Cancer Centers. “It was a small cadre of folks who wanted to share ideas and opinions, tools, products, and programs,” says Lenora Johnson, director of NCI’s Office of Education and Special Initiatives. But now, with more than 100 members from 54 Cancer Centers—as well as an offshoot Canadian version of CPEN—the network is setting forth in 2005 as an independent professional organization, expanding its outreach and providing expertise to cancer educators throughout the United States.

Diane D. Cole recalls some of the early days of CPEN, which she joined in 1996 after becoming an education coordinator for the University of Virginia Cancer Center. “There were only about 30 people at the annual meeting that year,” she says, “but I really found it to be an incredible opportunity to learn so much from the experiences of

the other people. I was drawn in very quickly to CPEN because the networking opportunities are invaluable.”

In addition to networking opportunities, another primary benefit CPEN offers members is its online listserv forum. Cole says the listserv was especially helpful when she submitted a call for advice on planning the redesign of her NCI-designated Cancer Center’s Web site. “I wanted to know how other centers handled the patient education component on their Web sites,” she says, “and we received 11 responses. I don’t know any other way I could’ve gotten that type of expert advice so quickly and easily.”

CPEN’s growth and success has forced a rethinking of the group’s status as an NCI-supported and -managed network. They have outgrown their informal status and transformed into a true professional organization, Lenora Johnson says. “We’ve spent the last few years working with CPEN on carving out an independent identity

and a role for the organization in the larger context of cancer education.”

Key to that independence and new identity is CPEN’s decision to include cancer patient educators outside of NCI-designated Cancer Centers. This includes promoting access to the listserv and inviting all cancer educators to CPEN’s annual meeting in November at the Wake Forest Comprehensive Cancer Center in North Carolina.

Those who are interested in working with CPEN can find out more at <http://cpen.nci.nih.gov>; the organization will launch a revamped Web site—independent of NCI’s site—in a few months. Jean A. Just, patient education director at The Ohio State University Comprehensive Cancer Center, says the new site will include “a section on evidence-based practices. The site will also provide current news and information about the field, including updates on the annual meeting as well as minutes from our different committee meetings, and different education tools that we’ve developed that might be useful to others.” ♦

Coming Soon: Cancer Center Profiles

Now that you’ve learned about the “why” and “how” of the NCI Cancer Centers Program, look forward to learning about “who” the Cancer Centers are through a new Bulletin feature, Cancer Center Profiles.

These profiles will run approximately every 6 weeks and provide an overview of each NCI-designated Cancer Center, with information about their history, clinical specialties, research activities, and new programs of interest to patients, investigators, and health care professionals.

Tentative schedule:

- April 19—University of Pittsburgh Cancer Institute (PA)
- May 31—Mayo Clinic Cancer Center (MN)
- June 12—UNMC Eppley Cancer Center (NE)
- August 16—Siteman Cancer Center (MO)
- October 18—Vanderbilt-Ingram Cancer Center (TN)

The *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads the national effort to eliminate the suffering and death due to cancer. Through basic, clinical, and population-based biomedical research and training, NCI conducts and supports research that will lead to a future in which we can identify the environmental and genetic causes of cancer, prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

For more information on cancer, call 1-800-4-CANCER or visit <http://www.cancer.gov>. *NCI Cancer Bulletin* staff can be reached at ncicancerbulletin@mail.nih.gov.