NATIONAL CANCER INSTITUTE

NCI Cancer Bulletin

Eliminating the Suffering and Death Due to Cancer

November 15, 2005
Volume 2 | Number 44

In this issue:

A Publication of the
National Cancer Institute
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
National Institutes of Health
NIH Publication No. 05-5498

http://www.cancer.gov

Updated Results Show Tamoxifen Continues to Prevent Breast Cancer

Updated results from the first-ever, large-scale breast cancer chemoprevention trial show that 5 years of tamoxifen (Nolvadex) decreases the risk of invasive and noninvasive breast cancer among women at increased risk, even after they've stopped taking the drug. According to the study authors, approximately 2.5 million women in the United States are at significant enough breast cancer risk that the potential benefit of prophylactic tamoxifen use significantly outweighs any potential risks.

The findings represent "a beginning from which a new paradigm for breast cancer prevention can evolve," says Dr. Bernard Fisher, principal investigator for the Breast Cancer Prevention Trial (BCPT). "Cohorts of women at increased risk for breast cancer, who could derive a net benefit from receiving tamoxifen, have been clearly defined."

The results may also dispel some perceptions about chemoprevention, says study co-author Dr. Leslie Ford, associate director of NCI's Division of Cancer Prevention.

"There is this notion that for cancer prevention, you have to take something for the rest of your life," she says. "In this study, the beneficial effects persisted beyond the last pill."

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Director's Update

Cancer Center Directors Helping to Chart Path to 2015

Last week, I was in Dallas with the National Cancer Institute's (NCI) senior leadership team to host a retreat of the directors of all NCI-designated Cancer Centers. This was the third such retreat and, as with the first two, its goal was to encourage frank discussions and gain honest input from the directors on some of the most pressing issues facing NCI.

The directors recognize the essential role the Cancer Centers must play if we are to eliminate the suffering and death due to cancer. However, there were concerns among many that the timeline is too ambitious. At the same time, they recognized the substantial opportunities for real progress in the years ahead and were supportive of working with NCI leadership to establish intermediate milestones for reaching the 2015 goal.

To this end, a small group of directors, led by Dr. John Mendelsohn from the University of Texas M.D. Anderson Cancer Center, will be convened to develop ways in which the Centers will advance the translation of past and future discoveries in molecular medicine into standards of practice within the local and regional

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(Tamoxifen continued from page 1)
The results, published in the November 16 *Journal of the National Cancer Institute*, come from the 7-year follow-up data on more than 13,000 women who participated in the NCI-funded BCPT, a randomized, double-blind trial led by the National Surgical Adjuvant Breast and Bowel Project that compared 5 years of regular tamoxifen use with placebo in women at increased risk of breast cancer.

Consistent with the initial results, the updated data revealed that, overall, tamoxifen reduced the risk of invasive and noninvasive breast cancer (by 43 and 37 percent, respectively). The reduction was seen in all of the preidentified trial subgroups, including those with a history of benign abnormalities such as atypical hyperplasia or lobular carcinoma *in situ*.

Although breast cancer risk was reduced across all age groups, a bright line of benefit versus risk of serious adverse side effects was seen for participants 49 years of age and younger. For example, overall, there was a threefold increased risk of endometrial cancer, but there was only a slight and statistically insignificant increase in women under 49. A similar trend was seen for vascular side effects. There was also a reduced risk of fracture.

"That's one of the big messages from this trial—that tamoxifen is being underused in women under 50 who are at increased risk," says Dr. Ford. "For those women, there are demonstrable benefits with minimal risk of serious side effects."

The initial results from the BCPT, published in 1998, showed a nearly 50-percent reduction in invasive and 45-percent reduction in noninvasive cancers. The findings led to tamoxifen being the first chemopreventive drug approved by the Food and Drug Administration (FDA).

But in the study, tamoxifen use also was associated with an increased risk of serious side effects, including endometrial cancer, pulmonary embolism, and deep-vein thrombosis.

The 7-year follow-up data, with an average follow-up of 74 months, suggest those risks continue. However, because the trial was unblinded after the initial results were released, it also may have introduced some bias into the side effects data, Dr. Ford notes, because women who found out they were on tamoxifen were more likely to pursue follow-up related to real or perceived symptoms of side effects.

Dr. Susan M. Domchek, an assistant professor of medicine at the Abramson Cancer Center of the University of Pennsylvania, says she often offers tamoxifen to appropriate patients, but "many decline to take it in this setting." So although educating clinicians about tamoxifen's benefits is still needed, "one of the major problems…is the reluctance of patients to take it," she says. "We can work on the first part more easily at this point than we can on the second." ◆

By Carmen Phillips

(Director's Update continued from page 1)
communities they serve so well. The group will report their recommendations on 2015 and a game plan to achieve them at the next Center Directors' retreat, scheduled for May 2006.

The Center Directors received updates on current NCI operations and priorities, including a presentation on management of the institute while I serve as Acting FDA Commissioner. Drs. John Niederhuber, Anna Barker, and Mark Clanton all discussed their roles during this interim period, and I believe the discussion provided a strong measure of reassurance that we are committed to continuity in leadership at NCI during this period.

The retreat also included an in-depth analysis of NCI's fiscal year 2006 projected budget. This presentation set the stage for a constructive discussion about how Center Directors can provide input into the formulation of NCI's scientific priorities—an important contribution during a time of increasing financial constraints.

We were fortunate to have Dr. Anthony Hayward of the National Center for Research Resources in attendance to answer questions about NIH's new Clinical & Translational Science Awards program. With the expanding importance of team science in conducting cutting-edge cancer research, this program provides an excellent opportunity for Cancer Centers to obtain substantial research funding to partner with multidisciplinary teams within and outside of their respective institutions.

The Center Directors' collective experience and unabated commitment to their institutions, as well as to quality research and patient care, makes this retreat an invaluable planning tool. I know I speak for the entire senior leadership team when I say we are fortunate to have access to such a talented group of individuals. It's their dedication, and the commitment to excellence they have imbued in the staff at their respective centers, that makes 2015 an attainable goal. ◆

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

Spotlight

New Smoking Cessation Agents Edge Toward Market

During the 29th annual Great American Smokeout on November 17, thousands of the 44.5 million U.S. smokers will try to quit—and many will fail. But as early as next year, they can look forward to a boost from new smoking cessation pharmaceuticals. Designed with a thorough understanding of nicotine's effect on the body, these drugs and vaccines appear promising, but "the big question is whether they will outperform nicotine patches and gums," says Dr. Scott Leischow, former chief of NCI's Tobacco Control Research Branch.

"We know that, if used properly, nicotine replacement helps people quit," Dr. Leischow continues. "But real-world use doesn't lead to the same kind of quit rates we see in placebo-controlled clinical trials."

A recent meta-analysis found that only 7 percent of smokers who tried nicotine replacement quit for good. Overall, only 2.5 percent of smokers who try to quit each year succeed. "That's too low," says Dr. Leischow, who left NCI this month to join the Arizona Cancer Center as deputy director. "There really is a significant need for new medications."

About 21 percent of Americans over the age of 18 smoke regularly. That's half of the rate seen in the 1960s, but still far short of the 12 percent goal set by the Healthy People 2010 initiative. About 180,000 people died from smoking-related cancers in 2004.

The drug rimonabant (Acomplia), developed by Sanofi Aventis, is closest to market. Earlier this year the company reported a 36-percent quit rate among 787 U.S. smokers in a phase III clinical trial. About 20 percent of the smokers quit when given placebo. The company expects FDA approval in 2006.

Sanofi is also seeking FDA approval to market rimonabant as a weight-loss drug. Trial data show that the drug does help smokers keep off extra pounds, a second incentive for those who want to quit but fear weight gain, notes Dr. Leischow.

Rimonabant is the first drug to target and block cannabinoid receptors in the brain. These receptors reinforce pleasurable behaviors, such as smoking and eating, and stimulate the dopamine reward circuit. Deeply connected to memory, emotion, and motivation, the circuit is disrupted in people with addictions.

Several other types of brain receptors play key roles in the reward circuitry, a finding that has led researchers to the antinicotine potential of two other brain drugs already on the market, selegiline (Eldepryl) for Parkinson's disease and moclobemide (Manerix) for depression. Both are in clinical trials for smoking cessation.

Pfizer's new drug, varenicline, takes another tack: mimicking nicotine to block its effects without activating the reward circuit. According to company data released in June, 48 percent of smokers who took varenicline for 7 weeks quit, compared with 17 percent on placebo. The trial of 500 smokers also found a 33-percent quit rate among those who took bupropion (Wellbutrin, Zyban), a drug marketed for depression and smoking cessation since 1997.

Varenicline works much like the natural compound cytisine, which is sold in Eastern Europe without prescription. Safety testing of the drug is under way in Poland.

Three other companies are ramping up for phase III trials of nicotine vaccines. Although still 5 or 6 years from market, according to Dr. Frank Vocci, director of the National Institute on Drug Abuse's Division of Pharmacotherapies and Medical Consequences of Drug Abuse, the vaccines intrigue researchers for their potential as treatment and prevention agents. Instead of boosting the immune system to fight off pathogens, nicotine vaccines stimulate antibodies that bind to and inactivate nicotine before it acts on the brain.

In a phase II trial, counseling plus the Nicotine-Qbeta vaccine, developed by Swiss company Cytos, helped 40 percent of smokers quit for at least 6 months; counseling plus placebo led to a 31-percent quit rate. In another phase II trial, NicVAX, developed by Nabi, helped 33 percent of smokers quit, compared with 9 percent for placebo.

Despite the promise of the new approaches, Dr. Leischow cautions smokers and health care professionals to avoid pinning all of their hopes on new medications. "Tobacco use is a true addiction," he says. "We know that motivation combined with counseling and medications is the best approach."

Smokers who want to quit should call 1-800-QUIT-NOW or go to www.smokefree.gov. ◆

By Brian Vastag

Cancer Research Highlights

Ovarian Cancer Screening With Ultrasound and CA-125 Finds Cancer, But Also Many False-Positives

A new NCI study shows that screening methods such as transvaginal ultrasound (TVU) and testing for the protein biomarker CA-125 can detect ovarian cancer, but can also produce many false-positive test results. The report on preliminary results from the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial appears in the November 15 *American Journal of Obstetrics and Gynecology.*

These results, the first on ovarian cancer screening from the ongoing multicenter PLCO Trial, are based on analysis of the participants' initial screening tests. CA-125 and TVU have been considered potential screening techniques, but studies to date have not shown that they can be effective and thus they are not currently recommended. The long-term goal of the PLCO Trial is to determine whether screening with TVU and/or CA-125 decreases ovarian cancer mortality in women ages 55 to 74.

Of the 28,816 women who underwent baseline screening, 1,338 (4.7 percent) had an abnormal TVU and 402 (1.4 percent) had an abnormal CA-125 blood test. Thirty-four women (0.1 percent) had abnormal results in both screening tests. Among the women with abnormal test results, 29 tumors were detected, 20 of which were invasive cancers.

"Ovarian cancer is a disease that is often fatal, and both patients and physicians are anxious to find ways to detect it at an earlier, more curable stage," said lead author Dr. Saundra Buys of the University of Utah. "However, the results from the initial year of screening show that TVU and CA-125 cannot currently be recommended for widespread use in the general population."

Gene Profiling Suggests New Classification for Ovarian Tumors

Researchers using DNA microarrays to analyze gene activity in several types of ovarian tumors have determined that a type called papillary serous low malignant potential (LMP) is distinctly different from high-grade ovarian tumors. Further, the results indicate that low-grade invasive ovarian tumors are more similar to LMP tumors than to high-grade ovarian tumors.

The team used a technique called laser capture microdissection to isolate tumor cells from about 80 ovarian tumor samples. Using the microarrays, the researchers identified genes involved in regulating cell growth and other critical activities that were overactive in high-grade tumors but not in the other types. The low-grade and LMP tumors had similar overall patterns of gene activity that were distinct from those of the high-grade tumors.

The findings, taken together, suggest that LMP and low-grade tumors may represent "a distinct classification of tumors rather than as precursors in the development of advanced high-grade malignancy," the researchers report in the November 15 *Cancer Research*.

The results could have implications for treatment. Currently, patients with low-grade tumors receive the same therapy as patients with high-grade tumors: surgery followed by chemotherapy. "It is not clear that women with low-grade ovarian tumors benefit from being treated with high-grade regimens," notes Dr. Michael Birrer, who heads NCI's Molecular Mechanism Section and led the study.

Being able to distinguish among different types of ovarian tumors might eventually allow women with low-grade serous tumors to have therapy specific to their cancer and be spared the side effects of combination chemotherapy used for high-grade tumors.

Most Men Can Father Children After Testicular Cancer

A majority of men treated for testicular cancer can naturally father children, concludes a study from Norway published in the November 2 *Journal of the National Cancer Institute*. The success rate varied from 81 percent for men followed with surveillance to 38 percent for men who were treated with high-dose chemotherapy. The overall success rate was 65 percent with a median follow-up of 11 years.

"[T]he ability to conceive and the time to conception reflected the intensity of treatment," write the researchers from five Norwegian cancer centers.

The team assessed 1,433 men treated for testicular cancer between 1980 and 1994. The participants were split into five treatment groups: the first received only orchiectomy (surveillance) while the others were treated with orchiectomy plus retroperitoneal lymph node dissection, radiotherapy, or low- or high-dose chemotherapy.

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(Highlights continued from page 4)

In an accompanying editorial, Dr. Scott Saxman, of NCI's Cancer Therapy Evaluation Program, writes that conventional retroperitoneal lymph node dissection, which frequently results in dry ejaculation, and high-dose chemotherapy (defined in the study as greater than 850 milligrams of cisplatin) are no longer standard treatments. They have been replaced by nerve-sparing surgery and lower overall doses of chemotherapy, which do not affect male fertility as severely as previous treatments.

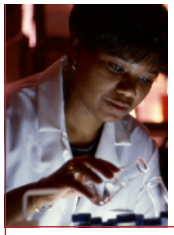
Newly diagnosed men concerned about having children should consider sperm banking, Dr. Saxman writes. Even those who choose surveillance instead of more intensive treatments should consider sperm banking, as some 20 to 30 percent of these men will experience disease recurrence and require aggressive chemotherapy. ◆

CCR Grand Rounds

November 22: Dr. Paul Meltzer, Senior Investigator, Cancer Genetics Branch, National Human Genome Research Institute; "Using Genome Technologies to Find Biological Mechanisms in Cancer: Beyond Expression Profiling"

November 29: Dr. Richard M. Caprioli, Stanley Cohen Professor of Biochemistry, Professor of Chemistry and Pharmacology, Director, Mass Spectrometry Research Center, Vanderbilt University; "The Role of Proteomics in Clinical and Biological Research: Direct Tissue Analysis by Mass Spectrometry"

CCR Grand Rounds are held 8:30 to 9:30 a.m. at the NIH campus in Bethesda, Md., in the Clinical Center's Lipsett Amphitheater. ◆



Featured Clinical Trial

Preoperative Radiotherapy for Retroperitoneal Sarcoma

Name of the Trial
Phase III Randomized Study of Surgery with or without Preoperative Radiotherapy in Patients with Primary Soft Tissue Sarcoma of the Retroperitoneum or Pelvis (ACOSOG-Z9031). See the protocol summary at http://cancer.gov/clinicaltrials/ACOSOG-Z9031.

Principal Investigators
Dr. Peter Pisters and Dr. Brian O'Sullivan, American College of Surgeons Oncology Group

Dr. Peter Pisters

Why Is This Trial Important?
Soft tissue sarcoma is cancer that starts in soft tissues of the body, such as the muscles, fat, tendons and other fibrous tissues, synovial tissues (tissues around the joints), and blood and lymph vessels.

Surgery is the primary treatment for patients with localized soft tissue sarcoma. Often, radiotherapy is used before or after surgery to improve the outcome of patients with soft tissue sarcoma of the head and neck or in an arm or leg. However, soft tissue sarcomas may also arise in the retroperitoneum, the narrow space between the abdominal cavity (which is lined by tissue called the peritoneum) and the posterior body wall. The retroperitoneum contains organs such as the kidneys, pancreas, and adrenal glands. The benefits of adding radiotherapy to surgery for retroperitoneal sarcoma are not clear.

In this trial, researchers are testing whether radiotherapy before surgery will help patients with retroperitoneal sarcoma survive longer without relapse of their cancer. Preoperative radiotherapy is thought to be more effective and less toxic than postoperative radiotherapy for this disease.

"Radiotherapy combined with surgery is the optimal treatment for most patients with sarcoma in an extremity, but we don't know yet if this combination is superior to surgery alone for retroperitoneal sarcoma," said Dr. Pisters. "This trial is designed to definitively answer that question."

Who Can Join This Trial?
Researchers seek to enroll 370 patients aged 18 and over with one of the specified primary soft tissue sarcomas of the retroperitoneum or pelvis. See the list of eligibility criteria at http://cancer.gov/clinicaltrials/ACOSOG-Z9031.

Where Is This Trial Taking Place?
Study sites in the United States and Canada are recruiting patients for this trial. See the list of study sites at http://cancer.gov/clinicaltrials/ACOSOG-Z9031.

Contact Information
See the list of study contacts at http://cancer.gov/clinicaltrials/ACOSOG-Z9031 or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). The call is toll free and completely confidential. ◆

An archive of "Featured Clinical Trial" columns is available at http://cancer.gov/clinicaltrials/ft-all-featured-trials.

Funding Opportunities

Academic Research Enhancement Award

PA-06-042

Application Receipt Dates (*new, competing continuation, revised, and supplemental applications):* Feb. 25, June 25, and Oct. 25, 2006; Feb. 25, June 25, and Oct. 25, 2007; Feb. 25, June 25, and Oct. 25, 2008.

This is a renewal of PA-03-053. This funding opportunity will use the R15 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3272. Inquiries: Dr. Christopher L. Hatch—ncirefof@dea.nci.nih.gov

Assay Development for High Throughput Molecular Screening

RFA-RM-06-004

Letter of Intent Receipt Date: Dec. 29, 2005. Application Receipt Date: Jan. 12, 2006.

This is a renewal of RFA-RM-05-011. This funding opportunity will use the R03 and R21 award mechanisms. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3281. Inquiries: Dr. Mark Scheideler—scheidelerm@ninds.nih.gov

Novel Technologies for *In Vivo* Imaging

PA-06-045

Application Receipt Dates *(new, competing continuation, revised, and supplemental applications):* Dec. 1, 2005; Apr. 1 and Aug. 1, 2006.

This is a renewal of PA-04-094. This funding opportunity will use the R41 and R42 award mechanisms. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3284. Inquiries: Dr. Guoying Liu—guoyingl@mail.nih.gov; Dr. Keyvan Farahani—farahank@mail.nih.gov; Dr. James A. Deye—deyej@mail.nih.gov; Dr. Houston Baker—bakerhou@mail.nih.gov

Novel Technologies for *In Vivo* Imaging

PA-06-046

Application Receipt Dates *(new, competing continuation, revised, and supplemental applications):* Dec. 1, 2005; Apr. 1 and Aug. 1, 2006.

This is a renewal of PA-04-094. This funding opportunity will use the R43 and R44 award mechanisms. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3285. Inquiries: Dr. Guoying Liu—guoyingl@mail.nih.gov; Dr. Keyvan Farahani—farahank@mail.nih.gov; Dr. James A. Deye—deyej@mail.nih.gov; Dr. Houston Baker—bakerhou@mail.nih.gov

NCI Phase II Small Business Innovation Research Renewal Awards for Cancer Diagnosis, Prevention, and Treatment

PA-06-051

Letter of Intent Receipt Dates: Mar. 1, July 1, and Nov. 1, 2006; Mar. 1, July 1, and Nov. 1, 2007; Mar. 1, 2008.

Application Receipt Dates *(new, competing continuation, revised, and supplemental applications)*: Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007; Apr. 1, 2008.

This is a renewal of PA-04-047. This funding opportunity will use the R44 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3282. Inquiries: Dr. Rosemary S. L. Wong—rw26f@nih.gov

NCI Phase II Small Business Technology Transfer Renewal Awards for Cancer Diagnosis, Prevention, and Treatment

PA-06-052

Letter of Intent Receipt Dates: Mar. 1, July 1, and Nov. 1, 2006; Mar. 1, July 1, and Nov. 1, 2007; Mar. 1, 2008.

Application Receipt Dates *(new, competing continuation, revised, and supplemental applications)*: Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007; Apr. 1, 2008.

This is a renewal of PA-04-047. This funding opportunity will use the R42 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3283. Inquiries: Dr. Rosemary S. L. Wong—rw26f@nih.gov

Basic and Preclinical Research on Complementary and Alternative Medicine (CAM) (R15)

PA-06-064

Application Receipt Dates: (n*ew, competing continuation, revised, supplemental applications):* Feb. 25, June 25, and Oct. 25, 2006; Feb. 25, June 25, and Oct. 25, 2007; Feb. 25 and June 25, 2008.

This is a renewal of PA-05-141. This funding opportunity will use the R15 award mechanism. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3287. Inquiries: Dr. Wendy B. Smith—smithwe@mail.nih.gov; Dr. Cindy Davis—davisci@mail.nih.gov ◆

Notes

Bhatia to Head NCI AIDS Malignancy Program

Dr. Kishor Bhatia was named director of NCI's new AIDS Malignancy Program (AMP), effective October 2. In his prior position, Dr. Bhatia served as a program director for NCI's Cancer Diagnosis Program in the Division of Cancer Treatment and Diagnosis (DCTD).

Under Dr. Bhatia's direction, AMP will support extramural HIV and AIDS malignancy research, and coordinate all AIDS and AIDS-oncology efforts across NCI. Existing AMP projects include the AIDS and Cancer Specimen Resource, Women's Interagency HIV Study, Multicenter AIDS Cohort Study, AIDS International Training and Research Program, and AIDS Malignancy Consortium. Dr. Bhatia also worked at NCI as a senior staff fellow and senior staff scientist.

NCI Seeks Information on Biospecimens

NCI and the National Human Genome Research Institute are pursuing a 3-year pilot project to conduct genomic characterization analyses and targeted sequencing of specific genes and genomic regions from human cancer biospecimens. The pilot project will assess the feasibility and value of this large-scale approach for the identification of genomic data with potential relevance to cancer, which could lead to the development of new drugs and improved tools for cancer detection, diagnosis, and treatment.

The purpose of this request for information (NOT-CA- 06-002) is to solicit responses from investigators who have collected well-annotated cancer biospecimens within the United States or internationally. For more information and instructions for replying, go to http://grants.nih.gov/grants/guide/notice-files/NOT-CA-06-002.html.

DTP Celebrates 50 Years

NCI's Developmental Therapeutics Program (DTP) is holding a day-long symposium on November 29 to celebrate 50 years of drug development know-how. Highlights include a panel discussion on the future role of NCI in cancer drug development and a poster session showcasing DTP's services and its long history of successes.

As the drug discovery and development arm of NCI, DTP plans, conducts, and facilitates development of therapeutic agents for cancer. For more information on DTP and symposium registration, go to https://secure.palladianpartners.com/dtp_symposium. The symposium, to be held at Lipsett Amphitheater on the NIH campus, will also be webcast live at http://videocast.nih.gov/.

NCI's Christian Receives Presidential Rank Award

Dr. Michaele Christian, associate director of DCTD's Cancer Therapy Evaluation Program, has received the 2005 Meritorious Executive Presidential Rank Award. President Bush recognized 278 outstanding federal executives this year with this, the government's highest award for civil servants. Each year, the President recognizes a group of career senior executives with this award for exceptional long-term accomplishments. Winners are nominated by their agency heads, evaluated by boards of private citizens, and approved by the President. For a full list of this year's Presidential Rank Award winners, go to http://www.opm.gov/ses/2005merit.asp.

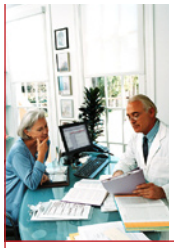
NCI Awards Grants for Translational Research

NCI recently awarded six grants to support research on translating molecular signatures of tumors to improve patient management and ultimately to improve patient outcomes. The grants are supported by the Strategic Partnering to Evaluate Cancer Signatures (SPECS) program. The grants support multi-institutional, multidisciplinary translational research teams that include investigators from the Clinical Co-operative Groups, SPOREs, Cancer Centers, NCI intramural laboratories, the National Laboratories, community hospitals, biotechnology companies, and individual academic institutions in the United States, Canada, and Europe.

SPECS will evaluate the potential clinical use of molecular signatures derived from comprehensive tumor analysis. The investigators will confirm and refine molecular signatures that have previously been shown to correlate with clinical parameters such as recurrence, survival, or response to therapy. They will develop reproducible assays that can be incorporated into clinical trials for validation of clinical utility.

Six grants totaling $10 million for the first year of funding were awarded to Children's Hospital Los Angeles; the University of California, Irvine; the University of Nebraska Medical Center; the University of New Mexico; Vanderbilt-Ingram Cancer Center; and Washington University's Department of Medicine.

For more information about the Cancer Diagnosis Program, go to http://www.cancerdiagnosis.nci.nih.gov. ◆



CCOP Profile

Wichita Community Clinical Oncology Program

Principal Investigator: Dr. Shaker Dakhil • Administrator: Marge Good
Via Christi Regional Medical Center, 929 N. St. Francis Street,
Wichita, KS 67214 • Phone: 316-268-5784

Background

The Wichita Community Clinical Oncology Program (CCOP), which first received funding by NCI in 1983, comprises two major community hospitals—Via Christi Regional Medical Center and Wesley Medical Center—and also has affiliations with the University of Kansas School of Medicine-Wichita, Wichita State University, Harry Hynes Memorial Hospice, and 11 other sites across Kansas. Through this consortium, the CCOP includes 11 medical oncologists; 6 radiation oncologists; 2 gynecologic oncologists; 1 pediatric oncologist; and 16 surgeons, urologists, and primary care physicians who have completed training on protection of research subjects. The program receives patient referrals from more than 175 additional physicians.

Members of the Wichita CCOP

Community Characteristics

Wichita is the largest population center in south central Kansas. As a result, the Wichita CCOP serves as the referral center for cancer care for the region, a mostly rural area. The program's affiliation with hospitals and clinics throughout the region allows patients access to the latest cancer protocols in or near their communities, and also provides training to oncologists who can then provide the latest care to patients who are not eligible for clinical trials.

Enrollment and Outreach

Though its patient base is small (approximately 850,000), during its 22 years the Wichita CCOP has registered a total of 9,200 patients to cancer clinical trials: 4,755 to treatment protocols and 4,445 to cancer control trials. In fiscal year 2005, the average monthly rates of enrollment were 35 patients for NCI treatment trials and 34 participants for NCI cancer control trials. Ninety percent of the patients who enroll in trials are referred by oncologists affiliated with the Cancer Center of Kansas.

The Wichita CCOP's percentage accrual of eligible patients is extraordinarily high. As a member of the Southwest Oncology Group, Wichita CCOP had the highest total accrual to cancer treatment trials between 1990 and 2004. And after only 4.5 years of membership in the North Central Cancer Treatment Group, Wichita CCOP is the highest accruer to cancer control trials and the third-highest accruer to treatment trials.

Wichita CCOP has had particular success enrolling minorities. Approximately 7.3 percent of patients enrolled in trials by Wichita CCOP are from a minority group—higher than the 6 percent of eligible minority patients in the region. For the STAR breast cancer trial, Wichita CCOP recruited 39 percent of eligible women from rural areas to participate. To boost representation in the future, the program has established partnerships with clinics in underrepresented regions and regularly sends staff to community events to educate attendees about the opportunity of cancer clinical trials.

Other Key Facts

Several deans, professors, and chairs of preventive medicine and internal medicine at the University of Kansas School of Medicine in Wichita are involved with the Wichita CCOP, either as investigators enrolling patients or as educators teaching students about the options for cancer patients and continuing medical education available through the program. Thus, Wichita CCOP cultivates referral relationships with local oncologists during their earliest years of training, making clinical trial recruitment a part of the regional standard of cancer care. ◆

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.