NATIONAL CANCER INSTITUTE

# NCI Cancer Bulletin

*Eliminating the Suffering and Death Due to Cancer*

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## "Stunning" Results of Breast Cancer Clinical Trials Published

Women with early-stage breast cancer who have extra copies of the gene *HER2* or its protein should be treated with chemotherapy and the drug trastuzumab (Herceptin), according to the results of three clinical trials reported in the October 20 *New England Journal of Medicine* (*NEJM*).

The results, from two trials in the United States and one in Europe, demonstrate that for many women with early-stage HER2-postive breast cancer, an aggressive disease that tends to recur, adding trastuzumab to chemotherapy can reduce the risk of recurrence by 50 percent compared with chemotherapy alone.

"We have made a radical advance in the treatment of breast cancer," says Dr. Edith A. Perez of the Mayo Clinic College of Medicine, who chaired the trial led by the North Central Cancer Treatment Group (NCCTG). "The publication of these results will show the tremendous impact this therapy has on people's lives now."

Preliminary results from the U.S. trials were reported in May at the American Society of Clinical Oncology annual meeting. The trials had been cut short after committees monitoring the interim results determined that trastuzumab plus chemotherapy was clearly

*(continued on page 2)*

*Director's Update*

Guest Update by Dr. John E. Niederhuber

## *No Time or Excuse for Stagnation*

The activity and energy level at NCI, as I've found over the past month, is astounding. Each week brings a significant event or announcement that has transformational potential. Take the recent announcements of awards to fund components of the NCI Alliance for Nanotechnology in Cancer and the Transdisciplinary Research on Energetics and Cancer centers: initiatives that could have wide-ranging effects for cancer patients and those at risk of cancer.

It's also rewarding to take part in essential NCI activities, especially community outreach. In just the past week, I met with leaders from the Association of American Cancer Institutes, the New York University Cancer Institute, and Cold Spring Harbor Laboratory to talk about NCI's programs and initiatives that are keeping us headed toward the 2015 goal.

It's tempting—and easy—to be skeptical about maintaining this level of activity during a period when the government has had to tighten its belt. I believe that would be a mistake. The National Cancer Program is as robust as ever and, in concert with the entire cancer community, we are ensuring it remains that way.

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*(Breast Cancer continued from page 1)*
superior to chemotherapy alone and should be made available to all participants.

The NCCTG trial and the National Surgical Adjuvant Breast and Bowel Project trial, both sponsored by NCI, evaluated regimens of doxorubicin and cyclophosphamide followed by paclitaxel with or without trastuzumab. In Europe, the Herceptin Adjuvant Trial compared chemotherapy followed by trastuzumab with chemotherapy alone.

The findings in *NEJM* include detailed information about trastuzumab's safety, which had been questioned because 3 to 4 percent of women experienced symptoms of heart disease. The majority of these symptoms improved immediately with treatment, according to the researchers.

"The important message is that the efficacy of this treatment is so dramatic that while the safety issues should be followed closely, the therapeutic benefit completely outweighs the risk of toxicity for women with this disease," says Dr. Perez.

Approximately 50,000 women in the United States are diagnosed with HER2-positive breast cancer each year, representing about 20 percent of invasive breast cancers. Extra copies of the *HER2* gene in tumor cells lead to abnormal levels of the HER2 protein.

Trastuzumab, made by Genentech, targets the mutant HER2 protein without causing damage to normal cells. In combination with chemotherapy, the targeted therapy alters the course of the disease, reversing a woman's prognosis from poor to good.

An editorial accompanying the studies calls the results "simply stunning." On the basis of these findings, "the care of patients with HER2-positive breast cancer must change today," writes Dr. Gabriel N. Hortobagyi of the University of Texas M.D. Anderson Cancer Center.

The editorial is "glowing" but deservedly so, says Dr. JoAnne Zujewski, who oversees breast cancer trials for NCI's Cancer Therapy Evaluation Program. It is now critical, she adds, that women diagnosed with breast cancer have their tumors tested by laboratories with validated technologies for detecting HER2 markers.

The researchers do not know whether women with small HER2-positive tumors would benefit from the treatment—or whether women diagnosed a year or longer ago would benefit. Future studies will further assess the risks and benefits of giving trastuzumab with chemotherapy or following chemotherapy.

Results from a fourth multicenter clinical trial now under way in the United States are to be presented in December at the San Antonio Breast Cancer Symposium. ◆

*By Edward R. Winstead*

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*(Director's Update continued from page 1)*

Currently the National Institutes of Health (NIH) and NCI are operating under a Continuing Resolution that keeps its agencies funded at 2005 levels until the 2006 budget is passed. Nevertheless, NCI is proceeding with the budget planning process—performing modeling based on a number of scenarios that will allow the institute to establish a 2006 budget that addresses our strategic priorities and funds essential new programs. During this process, I have focused on maintaining the number of competing grants to be funded in 2006 as close as possible to that of prior years, while also working to ensure that an appropriate number of new investigator grants are funded. It is crucial that we continue to develop the next generation of cancer researchers.

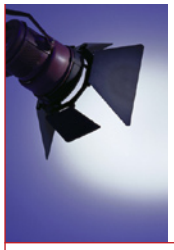
Lean budgets are no excuse for stagnation. With proper planning, I expect that we can continue to accelerate our progress. This optimism is based on a number of factors, including regular advances like the recently reported success with the targeted agent trastuzumab in treating early-stage breast cancer.

My optimism is also rooted in the strategic initiatives under way at NCI paving the way for progress. In the clinical trials arena, for instance, implementation plans have been written for all of the recommendations from the Clinical Trials Working Group. These recommendations will reinvigorate and modernize NCI's clinical trials program so that we can get more promising agents through clinical trials and to patients more effectively and efficiently.

Then there is the human cancer genome pilot, for which NCI and the National Human Genome Research Institute continue to plan. This effort will expand our knowledge of the molecular foundations of several cancers and determine whether a larger scale cancer genome project is feasible and how best to design it.

But whether it's well-designed initiatives and programs in imaging, informatics, tobacco control, survivorship, or molecular epidemiology—they all point toward a future of tremendous gains against cancer.

Undoubtedly, whether budgets are flat or expanded, disciplined stewardship of funds is essential. Our focus now, as always, is on making sound, strategic decisions that advance NCI's agenda and mission and, more importantly, providing the utmost benefit to the patients who are counting on us. ◆



# Spotlight

## HHS Takes a Community Approach to Networking EHRs

To bring the advantages of modern technology—with greater safety, convenience, and economy—into the health care arena, President Bush has asked the federal government to develop a nationwide electronic health records (EHR) system within 10 years. But to maximize the benefit of EHRs, the system must enable information to reach all those who need it (and are authorized to use it) to improve health and health care—including patients themselves. To mobilize key stakeholders and address the technical and policy challenges from diverse perspectives, HHS Secretary Mike Leavitt recently organized an advisory group, the American Health Information Community.

The group met with Secretary Leavitt for the first time on October 7 for a comprehensive discussion, characterizing benefits that consumers could realize through EHRs in as little as 2 to 3 years.

The move to digitize health information is already well under way in the public and private sectors. Large hospitals have been developing EHRs to help manage patients between inpatient and outpatient settings. (See *NCI Cancer Bulletin,* June 21.) On the federal front, the Department of Defense has been using an EHR system since the early 1990s, and the Veterans Health Administration has been using one, known as VistA, since the 1980s. VistA was recently adapted by the Centers for Medicare & Medicaid Services for use among small physician practices.

But in light of the current push for nationwide EHRs, one of the challenges will be aligning existing systems with new technology, and vice versa. This process is being performed on multiple fronts, with leadership by Dr. David Brailer, national coordinator for Health Information Technology, and advisor to Secretary Leavitt in this capacity.

At NCI, relevant projects—including the cancer Biomedical Informatics Grid (caBIG) and SEER (Surveillance, Epidemiology, and End Results) program—are contributing to the national system by building an interoperable cancer information network, tools, and databases that make biomedical and clinical information available more quickly and easily than was previously possible. "Through caBIG, clinicians and researchers from around the country could ultimately use information that has been gathered from diverse sources across the nation, all to help determine the best approach for treating a specific cancer patient," explains Dr. Ken Buetow, who oversees caBIG as director of NCI's Center for Bioinformatics.

To ensure that NCI initiatives are closely aligned with HHS efforts, NCI staff play lead roles in key HHS groups, including the National Health Information Infrastructure Workgroup, the Federal Health Architecture, and the Consolidated Health Informatics Initiative. "Our goal with caBIG is to be sure that we're coordinating and collaborating with other federal activities, but also to enable them to learn lessons from us where it's helpful," says Dr. Buetow.

The Community will continue to meet with Secretary Leavitt every 4 to 6 weeks. Upcoming tasks include establishing workgroups to address biosurveillance, chronic disease monitoring, and consumer-driven electronic records, as well as continuing to discuss quality monitoring and reporting and e-prescribing technology.

In the meantime, the government is intensifying its push toward the 10-year goal through funding. On October 6, the Agency for Healthcare Research and Quality awarded 16 project planning grants totaling $22 million to prepare rural and underserved communities to adopt EHRs. HHS also awarded three contracts to public-private groups for $17.5 million to harmonize data standards, develop criteria for certifying compliance with those standards, and develop conformance solutions to patient privacy regulations.

In terms of the cancer-focused work being done through SEER and caBIG, Dr. Mark Clanton, NCI deputy director for Cancer Care Delivery Systems, says that a national EHR will dramatically improve the impact of these tools, as well as the quality of care and quality of life for cancer patients. "With access to a patient's full medical history, clinical trial investigators and health care providers will be able to make more informed decisions about the appropriateness of a trial for an individual patient and to adjust treatment to each patient's needs," he says. ◆

*By Brittany Moya del Pino*

# Cancer Research Highlights

## Genetic Test for *BRCA1* and *2* Benefits High-Risk African American Women

African American women at high risk for breast cancer because of their family history will benefit from genetic testing, report researchers from the University of Chicago Medical Center. One of the first major studies to examine the value of testing across different ethnic groups for the *BRCA1* and *BRCA2* gene mutations, its findings were published in the October 19 *Journal of the American Medical Association.*

The researchers found, after DNA sampling, that significantly more non-Hispanic, non-Jewish whites had one of the nearly 50 known *BRCA1/2* mutations (46.2 percent), but also found mutations in 27.9 percent of African American women. Yet African Americans were nearly four times as likely to have a variant in these genes that is not known to—but could—be a breast cancer susceptibility mutation. Dr. Rita Nanda and colleagues write that "unfortunately, there is a paucity of data about…the functional consequences of these variants."

The BRCAPRO risk assessment tool worked in predicting which African American women were likely to have a *BRCA1/2* mutation (which would be discovered by subsequent genetic testing) as well as it did for white women, Ashkenazi Jewish women, and the overall study population of 155 families that were identified by the statistical model.

Among all women in the study, early age at diagnosis of breast cancer was associated with an increased likelihood of carrying a *BRCA1/2* mutation. A woman's chance of having a mutation increased relative to how many of her close relatives had been diagnosed with breast or ovarian cancer.

## CD19-Targeted Monoclonal Antibody Looks Good in Animal Model

A new monoclonal antibody that targets B cells could prove to be as effective as rituximab (Rituxan) for treating non-Hodgkin lymphoma (NHL), as well as other lymphomas and leukemias, Duke University researchers are reporting. Many lymphomas and leukemias are of B cell origin.

In a study published October 10 in the early online edition of the *Proceedings of the National Academy of Sciences*, Dr. Thomas Tedder and colleagues report that, in mouse models, use of monoclonal antibodies (mAbs) that target a protein on the surface of B cells called CD19 was highly effective at eliminating B cells—both mature cells as well as precursor and immature B cells. Rituximab, which targets the CD20 protein on B cells, only aids in the depletion of mature B cells. It is effective in approximately half of NHL patients.

In addition, use of the CD19-targeted mAbs in 10 mice with malignant B cell lymphomas eliminated the presence of tumor cells in the circulation and tissue for up to 7 weeks, the study found.

While some earlier efforts were made to target CD19, they were limited by various shortcomings. Since those experiments, the mechanism by which antibodies to proteins such as CD20 and CD19 aid the immune system in killing cells is better understood. "Now we know the mechanism, we know how to choose the patients better, we know how to choose better antibodies, and we've done the pharmacokinetics and dosing," says Dr. Tedder.

Planning is underway to test the CD19-targeted mAbs in early clinical trials through a company Dr. Tedder founded, and which was recently purchased by the biotechnology company MedImmune.

## ADHD Symptoms Linked to Likelihood of Smoking in Young Adults

Researchers from Duke University examining the relationship between reported attention-deficit hyperactivity disorder (ADHD) symptoms in young adults and smoking behaviors found a significant relationship between the number of reported ADHD symptoms and lifetime regular cigarette smoking, according to study results published in the October issue of *Archives of General Psychiatry.*

The analysis included 15,197 participants from wave III of the National Longitudinal Study of Adolescent Health, a nationally representative sample of adolescents followed from 1995 to 2002, which is primarily funded by the National Institute of Child Health and Human Development. Controlling for demographic and conduct disorder symptoms, each retrospectively reported symptom of ADHD inattention and hyperactivity/impulsivity significantly increased the likelihood of ever regularly smoking. However, hyperactivity/impulsivity

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symptoms were found to be a better predictor of lifetime regular smoking than inattention symptoms, even in individuals reporting subclinical ADHD symptoms.

The findings suggest that self-reported ADHD symptoms are associated with the age of onset of regular smoking and support other studies associating ADHD with increased risk of smoking.

## Suppression of Type I Collagen Synthesis Limits Angiogenesis

Angiogenesis—the formation of new blood vessels—is required for the growth and repair of normal tissue. This process can be used by cancer cells, allowing tumors to commandeer oxygen and nutrients needed for growth. Scientists are searching for the molecular pathways responsible for the angiogenic switch—the point at which a tumor begins creating its own network of blood vessels.

A new study by NCI researchers implicates loss of thrombospondin-1 (TSP1), an angiogenesis modulator, and subsequent upregulation of type I collagen as important components of new blood-vessel formation.

Investigators established an *ex vivo* model of endogenous TSP1 loss using tissue explants from transgenic mice lacking the molecule. Upregulated type I collagen expression was found to be dependent on the lack of endogenous TSP1, and treatment with exogenous TSP1 suppressed collagen Iα1 and Iα2 levels. In turn, this suppression of type I collagen inhibited angiogenesis in the explants. Blocking mRNA expression for collagen Iα1 or Iα2 also inhibited blood-vessel growth. These results suggest blocking type I collagen expression may be an effective anti-angiogenic therapy.

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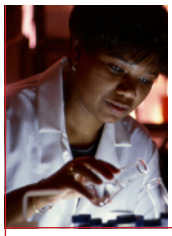

# Featured Clinical Trial

## Chemotherapy for Previously Treated CLL

**Name of the Trial**
Phase II Study of Flavopiridol in Patients with Previously Treated B-Cell Chronic Lymphocytic Leukemia (CLL) or Prolymphocytic Leukemia Arising from CLL (CLLRC-OSU-0491). See the protocol summary at http://cancer.gov/clinicaltrials/CLLRC-OSU-0491.

**Principal Investigator**
Dr. John Byrd, The Ohio State University and the CLL Research Consortium

**Why Is This Trial Important?**
Chronic lymphocytic leukemia (CLL) is a slowly progressing cancer in which too many white blood cells (lymphocytes) are found in the blood and bone marrow. The disease primarily affects middle-aged and older adults. Treatment for CLL depends upon the stage of the disease and may include chemotherapy, radiation therapy, surgery, stem cell transplantation, or some combination of therapies.

In this clinical trial, researchers are testing the ability of a drug called flavopiridol to cause the remission of CLL that arises in a class of lymphocytes called B cells. In previous studies, flavopiridol was shown to stop the growth of CLL cells and cause apoptosis (cell "suicide"). Researchers hope that flavopiridol will help induce disease remission in patients whose CLL has recurred following previous treatment with other chemotherapy drugs.

"Flavopiridol kills CLL cells that are resistant to other therapies and that bear the genetic features that typically predict a poor response to treatment," said Dr. Byrd. "Unlike many new trials for relapsed and refractory CLL, where we are uncertain of the clinical activity, flavopiridol has already demonstrated dramatic and durable responses in some patients."

*Dr. John Byrd*

This trial will also test flavopiridol in patients with prolymphocytic leukemia (PLL), a more rapidly progressing type of CLL in which immature lymphocytes proliferate in the blood and bone marrow.

**Who Can Join This Trial?**
Researchers seek to enroll 17 to 32 patients aged 18 or over with confirmed B-cell CLL or PLL who have received prior treatment for their disease. See the list of eligibility criteria at http://cancer.gov/clinicaltrials/CLLRC-OSU-0491.

**Where Is This Trial Taking Place?**
Multiple study sites in the United States are recruiting patients for this trial. See the list of study sites at http://cancer.gov/clinicaltrials/CLLRC-OSU-0491.

**Contact Information**
See the list of study contacts at http://cancer.gov/clinicaltrials/CLLRC-OSU-0491 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

## Environmental Influences on Epigenetic Regulation

RFA-ES-05-007

Letter of Intent Receipt Date: Dec. 19, 2005. Application Receipt Date: Jan. 18, 2006

This funding opportunity will use the R01 and R21 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3268. Inquiries: Dr. Mukesh Verma—vermam@mail.nih.gov; Dr. Sharon A. Ross—rosssha@mail.nih.gov

## Small Business Innovation Research to Improve the Chemistry and Targeted Delivery of RNAi Molecules (SBIR [R43/R44])

PA-06-003

Application Receipt Dates: *New, competing continuation, revised, supplemental applications:* Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007. *AIDS and AIDS-Related Applications (New, competing continuation, revised, and supplemental):* Jan. 2, May 1, and Sept. 1, 2006; Jan. 2, May 1, Sept. 1, 2007; Jan. 2, 2008.

This is a renewal of PA-05-041. This funding opportunity will use the R43 and R44 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3262. Inquiries: Dr. Suresh K. Arya—aryas@exchange.nih.gov

## Small Business Technology Transfer to Improve the Chemistry and Targeted Delivery of RNAi Molecules (STTR [R41/R42])

PA-06-004

Application Receipt Dates: *New, competing continuation, revised, supplemental applications:* Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007. *AIDS and AIDS-Related Applications (New, competing continuation, revised, and supplemental):* Jan. 2, May 1, and Sept. 1, 2006; Jan. 2, May 1, and Sept. 1, 2007; Jan. 2, 2008.

This is a renewal of PA-05-041. This funding opportunity will use the R41 and R42 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3263. Inquiries: Dr. Suresh K. Arya—aryas@exchange.nih.gov

## Small Business Innovation Research Program Parent Announcement (SBIR [R43/R44]): Electronic Submission of Grant Applications through Grants.gov

PA-06-006

Application Receipt Dates: *Non-AIDS applications:* Dec. 1, 2005; *AIDS and AIDS-related applications:* Jan. 2, 2006.

This funding opportunity will use the R43 and R44 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3264. Inquiries: Michael Weingarten—mw498z@nih.gov

## Small Business Technology Transfer Program Parent Announcement (STTR [R41/R42]): Electronic Submission of Grant Applications through Grants.gov

PA-06-007

Application Receipt Dates: *Non-AIDS applications:* Dec. 1, 2005; *AIDS and AIDS-related applications:* Jan. 2, 2006.

This funding opportunity will use the R41 and R42 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3265. Inquiries: Michael Weingarten—mw498z@nih.gov

## Bioengineering Nanotechnology Initiative (STTR [R41/R42])

PA-06-008

Application Receipt Dates: *New, competing continuation, revised, supplemental applications:* Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007; Apr. 1 and Aug. 1, 2008. *AIDS and AIDS-Related Applications (New, competing continuation, revised, and supplemental):* Jan. 2, May 1, and Sept. 1, 2006; Jan. 2, May 1, and Sept. 1, 2007; Jan. 2 and May 1, 2008.

This is a renewal of PA-02-125. This funding opportunity will use the R41 and R42 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3266. Inquiries: Dr. Piotr Grodzinski—grodzinp@mail.nih.gov. Shane Woodward—woodwards@mail.nih.gov

## Bioengineering Nanotechnology Initiative – SBIR (R43/R44)

PA-06-009

Application Receipt Dates: *New, competing continuation, revised, supplemental applications:* Dec. 1, 2005; Apr. 1, Aug. 1, and Dec. 1, 2006; Apr. 1, Aug. 1, and Dec. 1, 2007; Apr. 1 and Aug. 1, 2008. *AIDS and AIDS-Related Applications (New, competing continuation, revised, and supplemental):* Jan. 2, May 1, and Sept. 1, 2006; Jan. 2, May 1, and Sept. 1, 2007; Jan. 2 and May 1, 2008.

This is a renewal of PA-02-125. This funding opportunity will use the R43 and R44 award mechanisms. For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3267. Inquiries: Dr. Piotr Grodzinski—grodzinp@mail.nih.gov. Shane Woodward—woodwards@mail.nih.gov ◆

# Notes

### NCI's Outstanding Mentors Recognized

On October 14, NCI's deputy directors announced the 2005 NCI Outstanding Mentor Awards and Mentors of Merit. These NCI investigators were nominated by their trainees and received the highest rankings in a competitive review by an advisory committee of postdoctoral fellows.

The Outstanding Mentor Award winners for 2005 are Drs. Graça Dores, Stephen Katz, and Patricia Steeg. The Mentors of Merit are Drs. Sheue-yann Cheng, Scott Durum, Susan Krebs-Smith, R. Mark Simpson, Maryalice Stetler-Stevenson, and Sandra Swain.

The Outstanding Mentor Award was created in 2001 to recognize NCI investigators who have proven exceptional in their commitment to fostering the independent careers of their fellows, students, and other trainees. It is presented each year to individuals who have made significant contributions toward developing and promoting the talented trainees who will become the next generation of scientists.

### NCI Represented at NIH Research Festival

Scores of NCI researchers joined the NIH Research Festival held on the NIH campus Oct. 18 through 21. Highlights included a plenary session from Dr. Shiv Grewal on RNAi, a hot topic in gene regulation, and posters from Dr. Haleem Issaq (analyzing estrogen levels in blood); Dr. Sudhir Varma (gene profiling to predict response to chemo- and radiotherapy); Dr. Michael Leistzmann (physical activity and risk of postmenopausal breast cancer); and Dr. Mark Parascandola (public interest in trying a "less harmful" cigarette).

Representatives from NCI's Division of Cancer Epidemiology and Genetics, Office of Communications, NCI/SAIC Frederick Research Technology Program, Office of Science Planning and Assessment, and Technology Transfer Branch staffed booths devoted to resources for intramural researchers. ◆

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"Several labs have previously identified type I collagen gene products as markers of tumor blood-vessel growth and tumor metastasis in human and mouse cancers," said Dr. David D. Roberts, of the Laboratory of Pathology in NCI's Center for Cancer Research, whose lab performed the research published in the October 10 early online edition of *Oncogene*. "The fact that these genes that encode a major structural component of cartilage are also key players in tumor angiogenesis and metastasis was not previously understood."

## Ireland's National Smoke-Free Law Proves Effective and Popular

In March 2004, the Republic of Ireland became the first nation in the world to implement a comprehensive smoke-free law covering all the nation's workplaces, including restaurants and bars. Now, two studies, funded in part by NCI, demonstrate the success of Ireland's landmark legislation.

A study in the October 17 *Tobacco Control* documents that the new law has led to a dramatic decline in smoking in all workplaces in Ireland and an increase in the proportion of Irish homes that are smoke-free. But the new law has had other positive effects, according to lead author, Dr. Geoffrey T. Fong, of the University of Waterloo in Canada. The study found widespread acceptance and support for the new law among Irish smokers; overall, 83 percent rated the smoke-free law a "good" or "very good" thing. Nearly half of Irish smokers said the new law had made them more likely to quit, and of those smokers who had quit after the new law went into effect, 80 percent reported that the law had helped them in the process.

"This study demonstrates that Ireland's comprehensive smoke-free workplace law is achieving its public health goals while also achieving a high level of acceptance among smokers," said Dr. Fong. "These findings support enactment of smoke-free workplace policies in countries around the world, as fears of a smoker backlash or lack of compliance are simply unfounded."

A related study in the October 17 *British Medical Journal* documents that Ireland's smoke-free law protects nonsmoking bar workers from exposure to the harmful effects of second-hand smoke (SHS). Compared with bar workers in Northern Ireland, which has no smoke-free law, bar workers in the Republic of Ireland had significantly less exposure to SHS and significantly improved respiratory health, study author Dr. Shane Allwright and colleagues reported.

"Comprehensive smoke-free laws effectively reduce SHS exposure and are widely accepted by the public, including many smokers," said Dr. Robert T. Croyle, director of NCI's Division of Cancer Control and Population Sciences, which funded the research. "This research is an excellent example of how empirical evidence can inform public health policy." ◆

# Community Update

## Where caBIG Leads, Industry Will Grow

When bioinformatics executive Dr. Amar Chahal attended the Industry Partners meeting on September 30 hosted by NCI's cancer Biomedical Informatics Grid (caBIG) program, he felt that a watershed moment had occurred. It opened up opportunities for his and other companies working to provide clinical trial information services to the fragmented markets in the cancer and biomedical research communities.

"The Industry Partners meeting reflects a change in caBIG from its previous focus on working only with Cancer Centers and academic institutions," noted Dr. Chahal, executive vice president of Velos, Inc. "It's a welcome change because we were one of the most dedicated attendees at caBIG meetings since its inception 2 years ago. Up until now, we could sit and watch but we couldn't 'play' in the caBIG space. Now we get to play, too, which is fantastic!"

Velos was founded in 1996 to provide software applications to support the electronic information transformation under way in health care from clinical practice and medical research (http://www.velos.com). "Our company focuses on the execution of clinical trials," Dr. Chahal explained. "We basically provide a software infrastructure that allows the trial sponsor to go global immediately. You set up a computerized information system to include the documents involved, the mission, what to disclose to various participants, patient selection criteria, and so on."

Initially, Velos executives considered focusing on serving the pharmaceutical and biotechnology sectors, he continued, but this model poses a problem for investigators when every drug company has its own systems and procedures for conducting clinical trials. It was especially confusing to clinicians who participate in several trials for different firms, Dr. Chahal recalled. "They had to remember 4, 5, or 6 passwords and learn 5 or 6 software systems, methodologies, and procedures. That's very burdensome and it's not practical."

When Velos first heard about the caBIG program in 2003, they were intrigued by the possibility for bringing widely accepted, public standards to the marketplace. "caBIG came to the party later than us but what it has done is provide real leadership that has been acutely lacking," Dr. Chahal commented. "It allows us to have central, objective goals to bring everybody together. Once the various players start coming together, caBIG becomes the unifying force."

The caBIG Industry Partners meeting attracted more than 200 representatives from biomedical and informatics companies to discuss and consider involvement in the caBIG program (*NCI Cancer Bulletin*, October 11). Dr. Chahal and his Velos colleagues were especially interested in the sessions on how to make their current clinical trials management system compatible with caBIG standards and tools. "By establishing standards and opening it up to industry, caBIG gives us great comfort because we can continue to develop markets beyond the cancer field," he added. "We feel this is the seminal area and the caBIG standards will be adopted easily beyond cancer." The industry needs to be involved in that standard-setting process, Dr. Chahal urged. "It's a chance for us to play a leadership role." ◆

### Featured Meetings and Events

A calendar of scientific meetings and events sponsored by the National Institutes of Health is available at http://calendar.nih.gov/cgi-bin/calendar. ◆

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.