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Lung Cancer Screening Study Spurs Optimism, Caution

New results from a large, observational study suggest that using spiral computed tomography (CT) to screen people at increased risk for lung cancer can detect the disease at an early stage and may increase the number of people who can be cured. Currently, the vast majority of lung cancer diagnoses aren't made until the disease is well advanced, and most of these patients die within 5 years.

Among participants in the study who received a diagnosis of lung cancer based on spiral CT screening and a resulting biopsy, 85 percent had stage I lung cancer (412 of 484),

and a statistically estimated 10-year survival among these patients was 88 percent. Among stage I patients who underwent surgery within 1 month of diagnosis, the estimated 10-year survival rate was 92 percent. Very few patients in the study, however, have been followed for 10 years.

Some researchers and members of the lung cancer advocacy community have suggested that the results represent a long-awaited breakthrough; others believe that the study, because it wasn't a randomized trial with an unscreened control arm, falls short of answering some critical questions.

(continued on page 2)

Director's Update

Help Choose the Next Roadmap Initiatives

I'd like to draw the entire cancer community's attention to a Request for Information (RFI) in the October 20 issue of *NIH Guide to Grants and Contracts*. This important **new RFI** is soliciting suggestions for new initiatives that will improve and accelerate biomedical and behavioral research and its impact on public health, to be implemented under the aegis of the **NIH Roadmap for Medical Research**.

The feedback generated will build the foundation from which five to eight new Roadmap initiatives will be launched, from within the currently projected Roadmap budget, beginning in Fiscal Year 2008.

With this RFI, NIH is reaching out to as broad an audience as possible—the scientific community, health professionals, patient advocates, and the general public—to amass a broad array of novel and transformative ideas. On behalf of the NCI leadership team, I encourage the entire cancer community to participate in this process, nominating novel ideas on topics such as new ways to overcome barriers to research, accelerate translation of scientific discoveries, and fill research gaps that do not fall within the mission of any single NIH Institute or Center (IC).

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(Lung Cancer continued from page 1)

The study was published in the October 26 *New England Journal of Medicine*.

“The results are potentially exciting,” said Dr. Gary Kelloff, a special advisor to NCI’s Cancer Imaging Program in the [Division of Cancer Treatment and Diagnosis](#).

“Although it isn’t possible to determine whether CT screening actually decreases mortality based on these results,” he said, “they do provide valuable information.”

That includes data to help determine the percentage of screened patients with suspicious lesions that will be confirmed as cancers and evaluate the role of various tests, such as bronchoscopies and PET scans, in confirming spiral CT results.

The study—the International Early Lung Cancer Action Project (I-ELCAP)—involved 31,567 people without symptoms indicative of lung cancer but who were considered to be at increased risk for the disease.

All participants underwent baseline screenings using spiral CT between 1993 and 2005. Based on specific protocols dictated by the baseline screening results, 27,456 patients underwent additional “annual” spiral CT screenings.

Initially launched with a focus on current and former smokers in the United States, I-ELCAP was eventually expanded to include some international sites and a broader at-risk group, including people with heavy exposure to secondhand smoke or workplace contaminants linked to lung cancer, such as asbestos.

“In a population at risk for lung cancer, such screening could prevent 80 percent of deaths from lung cancer,”

wrote the study’s lead author, Dr. Claudia Henschke of Weill Medical College of Cornell University, and colleagues.

The results, said Dr. Denise Aberle, a professor of radiology at the UCLA Jonsson Comprehensive Cancer Center, “raises great hope for CT screening” for the early detection of lung cancer.

Along with Dr. Christine Berg from NCI’s [Division of Cancer Prevention](#), Dr. Aberle is a co-principal investigator on the NCI-sponsored National Lung Screening Trial (NLST), which is comparing spiral CT and chest x-ray in a population of more than 50,000 to determine which offers a stronger mortality benefit when used as a screening tool in current and former smokers.

Dr. Aberle cautioned that the findings can’t be construed as proof that spiral CT decreases the risk of death from lung cancer because the study provides only an estimate of survival based on a median of 3.3 years of follow-up.

“Survival statistics are entirely appropriate when used to compare differences in treatment modalities in patients with the same stage of a condition who are randomized to different treatment arms,” she explained. But using a survival endpoint to infer a screening benefit can be misleading, she continued. For example, by diagnosing disease in advance of symptoms, survival will increase even if there is no delay in death.

“These results punctuate the critical necessity of addressing the effectiveness of screening by determining mortality differences in a randomized trial,” said Dr. Kelloff. ♦

By Carmen Phillips

(Director’s Update continued from page 1)

The Roadmap is often described as an “incubator space” for initiatives that cut across scientific disciplines but that also represent “high-risk” projects that, under normal circumstances, might not be funded. That framework will continue with this new batch of initiatives.

In formulating your suggestions, please take special note of the inclusion criteria outlined in the RFI and that responses must be submitted by **November 17**.

I’ve already had an opportunity to participate in this endeavor. This summer, along with NIH Director Dr. Elias Zerhouni and National Institute of Mental Health Director Dr. Thomas Insel, I co-chaired one of five “consultation sessions” that represented the first phase of the process to identify these new initiatives. During these sessions, participating scientists, who represented a broad range of disciplines, discussed major impediments to rapid advances in biomedical research and how to possibly overcome them.

The second phase entailed all IC directors submitting their top ideas/initiatives for consideration. This RFI is the last, and perhaps most important, phase. In addition to submitting ideas, I also encourage you to review and [provide feedback](#) on the ideas nominated to date via the consultation sessions and IC Directors.

By the spring of 2007, all of the new ideas generated via this three-phase process will have been vetted, grouped into topic areas, and prioritized by the NIH IC Directors and the NIH Director, who will consult with the Advisory Council to the Director prior to selection of an FY08 cohort of new initiatives.

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Cancer Research Highlights

Sunitinib Benefits Patients with GIST after Imatinib Fails

In January, the Food and Drug Administration (FDA) [approved sunitinib \(Sutent\)](#) for treating gastrointestinal stromal tumor (GIST) in patients who develop resistance to or cannot tolerate primary treatment with [imatinib \(Gleevec\)](#). Final results from the trial that led to the approval appear in the October 14 issue of *The Lancet*.

The multicenter, randomized trial, led by Dr. George Demetri of the Dana-Farber Cancer Institute, was terminated early after a scheduled assessment of the data clearly favored [sunitinib](#) over placebo. The median time the disease took to progress for the sunitinib group was 27.3 weeks compared with 6.4 weeks for the placebo group. Patients in the sunitinib group had longer overall survival, even though the drug was available to all patients once GIST had progressed.

After the trial began, evidence emerged to suggest that discontinuing imatinib in patients with GIST may increase the risk of disease progression. But in the absence of a trial to directly compare sunitinib with the continuation of imatinib, “no definitive conclusion about the superiority of switching to sunitinib can be reached,” the authors wrote. They point out, however, that progression-free survival obtained with sunitinib in this study (24.6 weeks) compared favorably with the overall benefits

reported with escalation of imatinib (11.6 weeks).

“We can conclude that sunitinib is more effective than placebo in the treatment of imatinib-resistant GIST,” wrote Dr. Heikki Joensuu of Helsinki University Central Hospital, Finland, in an accompanying editorial. “The benefits of sunitinib are, however, only moderate in this setting, and might have been less if imatinib had been continued in the control arm.” Dr. Joensuu noted that several promising agents are being evaluated for treating GIST when the tumor no longer responds to imatinib, and these studies might bring further good news in the near future for patients with GIST.

Cognitive Behavior Therapy Helps Survivors Overcome Fatigue

Posttreatment fatigue is a common and debilitating side effect faced by many cancer survivors. A new study published in the October 20 *Journal of Clinical Oncology* reports that cognitive behavior therapy (CBT), a form of psychotherapy, can be an effective tool for fighting persistent posttreatment fatigue. This randomized, controlled trial was the first such trial to look at the management of postcancer fatigue.

Ninety-eight eligible patients 65 years of age or younger who had persistent fatigue with no discernable physiologic cause and who had completed cancer treatment at least 1 year before the start of the study were randomly assigned to receive either

CBT or assignment to a wait-list control group. CBT was tailored for each patient based on six identified perpetuating factors for postcancer fatigue: insufficient coping with the experience of cancer, fear of disease recurrence, dysfunctional cognitions concerning fatigue, dysregulation of sleep, dysregulation of activity, and low social support and negative social interactions.

Fatigue severity, functional impairment, and psychological stress were measured before and after therapy. Patients in the CBT group received an average of 12.5 sessions of therapy and experienced both statistically and clinically significant reductions in fatigue, functional impairment, and stress compared with the control group.

“The results show that CBT is successful in treating fatigue in cancer survivors,” wrote the authors. Further studies are needed, they noted, to determine the usefulness of CBT in older survivors and in patients with tumor types not represented in this study, to control for the lack of human contact experienced by patients in the control group, and to quantify the long-term effects of CBT.

African American Race Linked to Lower Breast Cancer Survival Rates

African American women with breast cancer who underwent a mastectomy and received either adjuvant or neoadjuvant systemic therapy were more likely to have larger, later stage tumors and lower survival rates than Hispanic and Caucasian women who received the same treatment, according to study results published online October 23 in *Cancer*.

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A Conversation with...Dr. Gary Kelloff

Dr. Gary Kelloff is a special advisor to NCI's Cancer Imaging Program in the Division of Cancer Treatment and Diagnosis.

How would you characterize the International Early Lung Cancer Action Program (I-ELCAP) results?

First, Dr. Henschke and her colleagues should be commended. The results suggest the optimism about potentially using spiral CT to screen at-risk patients for lung cancer is well founded.

But, to make truly informed decisions and policy about lung cancer screening, we must understand certain things, even beyond whether it actually decreases mortality, such as the disease's natural progression and the long-term effects of screening-driven interventions. We still don't have this information.

For example, when small nodules are found in screening participants, without invasive follow-up there is no way to distinguish nodules that could progress to a deadly cancer. We also don't have a clear definition of who is at high risk for developing lung cancer. NCI is working to develop validated risk models that will help identify those at highest risk who might benefit most from screening.

Will the National Lung Screening Trial (NLST) address these types of issues?

Because it's a randomized trial with more than 53,000 participants, NLST is different than I-ELCAP in several important ways. NLST should provide definitive evidence about whether there is a true mortality benefit associated

with lung cancer screening using CT or chest x-ray.

NLST will also help to answer questions about the medical resources required for follow-up on screening results, the effect of screening on quality of life, and its influence on smoking behaviors and beliefs. NLST is also developing a collection of specimens that is expected to be a valuable resource for years to come.

This is a complex issue. What should the public take away from all of this?

First, for anybody who is still smoking, the most effective way to reduce your risk of lung cancer **is to stop**.

Second, we just don't know if early diagnosis of lung cancer by spiral CT reduces deaths from the disease, but many people concerned about their lung cancer risk may seek screening. The decision to be screened for lung cancer is an individual one, so it's important that these individuals discuss this with their health care provider, who can assist in weighing the pros and cons for their situation.

It's also important to understand that lung cancer screening is not a test, but a process. Screening results lead to diagnostic workups, which may include follow-up CT scans and/or a lung biopsy. Lung biopsies pose their own risks, and can result in significant complications. Individuals who do get screened should do so at facilities with extensive screening expertise and experience. ♦

(Highlights continued from page 3)

Researchers at the University of Texas M.D. Anderson Cancer Center retrospectively analyzed data from two cohorts of patients who were treated prospectively in clinical trials at that institution between 1975 and 2000. The cohorts consisted of 1,456 women who were treated with doxorubicin-based chemotherapy following mastectomy (adjuvant therapy) and 684 women who were treated with doxorubicin-based chemotherapy before mastectomy (neoadjuvant therapy).

African American women treated with adjuvant chemotherapy had a 10-year overall survival rate of 52 percent, while Hispanic and Caucasian women had a survival rate of 62 percent. Similarly, African American women treated with neoadjuvant chemotherapy had a 10-year survival rate of 40 percent, compared with 56 percent for Hispanic and 50 percent for Caucasian women. More African American women treated with either adjuvant or neoadjuvant chemotherapy entered the clinical trials with later stage disease, tumors greater than 5 centimeters, and estrogen receptor-negative disease, which is considered more difficult to treat.

"These findings should prompt additional research on how we can improve outcomes for African American patients by understanding and addressing tumor biology," said lead author Dr. Wendy Woodward. "It's important to identify unique features in different populations and subgroups of all women with breast cancer so we can understand a woman's risk and factors that affect her care on an individual level." ♦



Spotlight

Stress Biology Yields New Opportunities

“Let me ask you this,” begins Dr. Steven W. Cole, “with all we know about how stress aggravates cardiovascular disease, promotes viral infections, exacerbates metabolic diseases, halts reproduction, and regulates the normal function of virtually every cell in the body, why would cancer cells somehow be exempt?”

As associate professor of medicine at UCLA, Dr. Cole makes the point rhetorically to his students, pointing them to the growing literature showing that prime actors in the human stress response—catecholamines and glucocorticoids—can regulate some key aspects of cancer biology. NCI, through the Basic and Biobehavioral Research Branch (BBRB) in the [Division of Cancer Control and Population Sciences](#), has supported much of this work.

“There’s not much evidence that stress directly causes cancer,” says Dr. Paige McDonald, acting chief of BBRB. “We know it is neither necessary nor sufficient to initiate the carcinogenic process.” But, she notes, recent studies have shown that stress hormones can accelerate the growth of established tumors.

“Human cancer is quite complex,” explains Dr. Anil Sood, professor of gynecologic oncology and cancer biology at the University of Texas M.D. Anderson Cancer Center. “Yet there are epidemiologic and experimental animal studies linking stress

to tumor growth. In advanced solid tumors, such as ovarian cancer, we thought that the impact of stress on tumor biology had to go beyond stress effects on the immune system.”

“Now we’re looking much harder at the direct impact of neuroendocrine hormones on the tumor itself,” says Dr. McDonald.

Recently, cancer biologists and psychologists have begun to work together to clarify how the brain interprets phenomena, releases hormones in response, and how those neuroendocrine factors may influence or regulate some of the key steps in tumor growth, including not only angiogenesis, but also cell proliferation, tumor invasion, and metastasis.

In an article published online July 23 in *Nature Medicine*, Dr. Sood and colleagues showed that—when exposed to catecholamines released by the sympathetic nervous system of mice put under stress—ovarian cancer cells that had been injected into the mice stimulated angiogenesis, increased in number, and began to metastasize.

Eventually Dr. Sood’s group not only described the genes, molecules, and pathways involved, but identified a new molecular target for slowing tumor progression—beta-adrenergic receptors expressed on the tumor cell surface. “We routinely try to recapitulate human disease in our models,” said Dr. Sood, “but we were surprised

that nearly all of the ovarian cancer cell lines we tested had receptors for the stress-produced hormones.”

Once they identified beta-adrenergic receptors as mediators of stress effects, the scientists tried to confirm what was happening by adding drugs that would either enhance or block those receptors. When they tried propranolol (Inderal), the effect of the stress-generated hormones was completely blocked. This nonspecific beta-blocker was originally marketed for high blood pressure. Dr. Sood’s results suggest that such beta-blockers may one day assume a role in adjuvant chemotherapy for cancer.

With results like this, the entire field of stress biology begins to take new shape. “Previously, the assumption was that stress is a psychological influence,” says Dr. Cole, “so its treatment should be at a psychological level, with elements such as psychotherapy, meditation, or guided imagery. This work suggests we might be able to protect cancer patients from the detrimental effects of stress using a pharmacologic approach.”

Work like Dr. Sood’s provides insight into the biochemical complexity of stress, and opens up the neuroendocrine system as a new context for developing strategies to combat the influence of stress hormones on cancer pathogenesis. NCI’s Ovarian Cancer Specialized Program of Research Excellence (SPORE) at M.D. Anderson is supporting much of this work as well, illustrating its clinical relevance.

Further evidence comes from an NCI-supported study at the University of Iowa. Dr. Susan Lutgendorf interviewed women about to undergo surgery for ovarian cancer, and then obtained fresh tissue (*Spotlight continued on page 6*)

(Spotlight continued from page 5)

samples from the tumor. Women who lacked social support and had higher levels of distress were found to have tumors with higher levels of vascular endothelial growth factor, demonstrating for the first time “an association between a psychological factor and a cytokine involved in tumor angiogenesis among patients with malignant disease,” she writes.

According to Dr. Cole, it makes sense that tumor cells would exploit stress biology because the healthy cells from which they develop often express receptors for catecholamines and glucocorticoids. A number of cancers are caused by viruses, and most cancer-related viruses have evolved DNA sequences that respond to either the corticoids or the catecholamines, he explains. “Stress biology is a niche into which many human pathogenic viruses have evolved,” says Dr. Cole.

These scientists recently published an article on stress regulation of tumor biology in the March 2006 issue of *Nature Reviews Cancer*, “The influence of bio-behavioural factors on tumour biology: pathways and mechanisms.” The experimental evidence supporting this perspective highlights the potential for novel therapeutic strategies that consider the role of stress on tumor growth and metastasis.

“Advances in cell biology and basic science have allowed us to see that cancer is not a homogenous disease,” says Dr. McDonald, “and we think this work has implications for many other cancers beyond the ovarian model discussed here, perhaps to most of the cancers that involve epithelial changes.” ♦

By Addison Greenwood



Featured Clinical Trial

Targeted Therapy for Ovarian Cancer

Name of the Trial

Phase III Randomized Study of Carboplatin and Paclitaxel Versus Carboplatin, Paclitaxel, and Concurrent Bevacizumab without versus with Extended Bevacizumab in Patients with Stage III or IV Ovarian Epithelial or Primary Peritoneal Cancer (GOG-0218). See the protocol summary at <http://cancer.gov/clinicaltrials/GOG-0218>.

Principal Investigators

Drs. Robert Burger and Gini Fleming, Gynecologic Oncology Group



Dr. Robert Burger

Why This Trial Is Important

Most women with ovarian cancer are not diagnosed until the cancer has spread to the peritoneum (the lining of the abdominal cavity) or beyond. The standard treatment for advanced ovarian cancer is surgery, both to establish the stage and type of cancer and to remove as much cancerous tissue as possible, followed by chemotherapy with drugs such as carboplatin and paclitaxel. Despite aggressive treatment, however, the survival rate for advanced ovarian cancer remains low.

In this trial, women who have undergone initial surgery for ovarian cancer or primary peritoneal cancer (which is biologically similar to ovarian cancer) will receive standard intravenous chemotherapy. Some women will also receive concurrent treatment with a biologic agent called bevacizumab. Bevacizumab blocks the activity of a protein called vascular endothelial

growth factor, which helps tumors form new blood vessels needed for continued growth and spread. Following chemotherapy, some of the bevacizumab-treated women will receive additional courses of bevacizumab.

“In earlier trials, bevacizumab was shown to shrink ovarian tumors and stop tumor progression in some women with recurrent ovarian cancer,” said Dr. Burger. “Based on these studies and studies of combining bevacizumab with chemotherapy for other advanced cancers, we’re undertaking this trial to see if concurrent bevacizumab or concurrent and extended bevacizumab will help women with advanced ovarian cancer live longer and delay time to tumor progression.”

Who Can Join This Trial

Researchers will enroll 2,000 women with suboptimal stage III or stage IV ovarian or primary peritoneal cancer who have undergone initial surgery for their cancer. See the list of eligibility criteria at <http://www.cancer.gov/clinicaltrials/GOG-0218>.

Study Sites and Contact Information

Study sites in the United States are recruiting patients for this trial. See the list of study contacts at <http://www.cancer.gov/clinicaltrials/GOG-0218>, or call the NCI’s Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for more information. The toll-free call is confidential. ♦

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



Gomez Honored by Avon Foundation

Dr. Jorge Gomez, chief of NCI's Organ Systems Branch in the Office of Centers,

Training, and Resources, received the 2006 Medical Advancement in Breast Cancer Award from the Avon Foundation on October 30. Dr. Gomez was honored for his work on the [Avon-NCI Progress for Patients](#) program, a 5-year, \$30 million partnership that currently encompasses 42 clinical trials that seek to expedite the application of new discoveries to benefit breast cancer patient treatment and care. Dr. Gomez referred to the program as "a flexible granting mechanism approach with fast decisions and an invaluable partnership with tremendous insight into the challenges of breast cancer research."

Niederhuber Addresses Cancer Center Directors

On October 24, NCI Director Dr. John Niederhuber addressed the leadership of many of the nation's cancer centers at the 2006 [Association of American](#)

[Cancer Institutes](#) (AACI) annual meeting in Chicago. Dr. Niederhuber discussed a variety of topics of interest to the cancer centers, including the effect of flattening budgets on the nation's cancer centers.

Barbara Duffy Stewart, AACI executive director, commented, "We are fortunate to have Dr. Niederhuber address our membership in his new role as NCI Director. We look forward to continuing our relationship with him and facilitating communication between NCI and the cancer centers in these fiscally challenging times."

SPN Monograph Available

The Special Populations Networks: Achievements and Lessons Learned 2000–2005, a monograph developed by NCI's [Center to Reduce Cancer Health Disparities](#), was recently published by *Cancer*. This monograph highlights the activities and accomplishments of the Special Populations Networks program (SPN), a 5-year, nationwide NCI-funded

program to reduce cancer health disparities in minority and medically underserved populations. The monograph is available online at <http://www3.interscience.wiley.com/cgi-bin/jissue/113386997>.



John Venditti Dies at 79

Dr. John M. Venditti, 79, who spent 26 years as chief of NCI's Drug Evaluation Branch during a 39-year career at the NIH, died on October 21 at his home in Bethesda, Md.

During the early 1950s, Dr. Venditti's laboratory work was instrumental in developing a number of anticancer

drugs. He was considered one of the world's leading experts on drug interactions and for many years was a member of NCI's Acute Leukemia Task Force. From 1966 to 1986, he directed the NCI anticancer drug screening program, a worldwide network of research and development projects for the discovery of improved chemotherapy. In 1983, he established National Cooperative Drug Discovery Groups, and directed the program until his retirement from government service in 1987.

Dr. Venditti received his undergraduate degree from the University of Maryland, and his doctorate in pharmacology from George Washington University. Dr. Venditti was an author on more than 160 scientific publications and several book chapters, and had been scientific editor of *Cancer Chemotherapy Reports*.

Survivors include his wife Nancy, three children, and three grandchildren. ♦

(Director's Update continued from page 2)

Based on the initial experience with the first round of NIH Roadmap initiatives—379 grants to 326 investigators—and some of the available results from the first round of Roadmap-funded projects, I believe this second wave will also produce significant advances.

I encourage members of the cancer community to learn more about the Roadmap's goals and areas of focus and to take advantage of such a unique opportunity to influence biomedical research and patient care. ♦

Dr. John E. Niederhuber
Director, National Cancer Institute

CCR Grand Rounds

November 7: Oncology

Nursing Lecture. Dr. Christine Miaskowski, Professor, Department of Physiological Nursing, University of California, San Francisco. "Symptom Clusters: The New Frontier in Symptom Management Research."

November 14: No lecture

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. ♦



Community Update

CTSU Increases Patient and Physician Access to Clinical Trials

Physicians seeking to enroll patients in NCI-sponsored Cooperative Group phase III adult treatment trials have improved access to these studies through the assistance of the Cancer Trials Support Unit (CTSU).

CTSU is an NCI program launched in October 1999 to provide clinicians across the United States and Canada with improved access to cancer treatment trials. The program was initiated following a systematic review of the clinical trials program at the time and led to the Board of Scientific Advisors approving the CTSU as a pilot project. Over the ensuing years, CTSU has become an integral part of the Cooperative Group system that is responsible for conducting most of NCI's phase III treatment trials.

CTSU recently underwent a competitive renewal. The original contractor, Westat, Inc., along with its subcontractor, the Coalition of National Cancer Cooperative Groups, was again selected to manage CTSU. In this second iteration, CTSU will continue to focus on making Cooperative

Group phase III treatment trials available to all Cooperative Group members and to selected sites that directly enroll via CTSU.

“Broad participation and rapid accrual have led to several important studies achieving results much faster than was possible before the advent of CTSU,” said Dr. Jeff Abrams, chief of NCI's Clinical Investigations Branch in the [Division of Cancer Treatment and Diagnosis \(DCTD\)](#) and CTSU co-project officer.

CTSU's programs and services include regulatory support, patient registration, clinical data management, help desk support, promotion, education and training, site performance evaluation, and site financial management.

“CTSU has expanded access to NCI-funded phase III trials that previously may not have been available at a given location, thus providing patients with additional treatment options,” noted Dr. Meg Mooney, head of Gastrointestinal Cancer Therapeutics for DCTD's Clinical Investigations Branch and CTSU co-project officer.

Before CTSU, investigators were limited to trials conducted by their own Cooperative Group or to specific intergroup trials. Investigators sent all regulatory materials to the Lead Cooperative Group and enrolled all patients through that Group's system. CTSU has increased physician and patient access by allowing Cooperative Group members to participate in trials coordinated by Groups to which they do not belong. CTSU has made it easy for investigators to participate in trials led by other Groups by creating a centralized location for investigators to submit regulatory documents, enroll patients, and access study documents.

Two trials that have enrolled patients more quickly than anticipated because of improved access via the CTSU are the ACOSOG Z9001 trial, a study looking at the use of imatinib (Gleevec) in gastrointestinal stromal tumors, and CALGB 90206, a study comparing the use of bevacizumab (Avastin) with interferon alfa-2B in advanced renal cell cancer—both of which have seen half or more of their enrollments enter via CTSU.

New challenges for this second edition of CTSU include creation of a centralized randomization hub for all its trials and the inclusion of trials from other NCI-sponsored trial networks, including phase II treatment studies, prevention and cancer control studies, and SPORE studies. More information about CTSU can be found at www.ctsu.org. ♦

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>. ♦

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>. Contact the *NCI Cancer Bulletin* staff at ncicancerbulletin@mail.nih.gov.