THE CANCER LETTER

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Cancer Trials Take 800 Days To Start On Average; NCI Vows Improvement

By Kirsten Boyd Goldberg

NCI and its clinical trials cooperative groups and cancer centers need to work together to cut the time it takes to activate cancer clinical trials, an Institute official told an NCI advisory group.

"It takes on average 800 days to go from an idea—the documentation of the idea—to the time the study is ready to go to a comprehensive cancer center to be initiated," said James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis.

"It takes another three to six months at a cancer center for it to open that trial," Doroshow said. "That's the median. If you look at the maximum [times], it's worse. In some cases it takes five years."

The time lag documented by Vanderbilt University researchers surprised

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In the Cancer Centers:

Frank Torti Named FDA Deputy Commissioner, To Take Leave As Wake Forest Center Director

FRANK TORTI was named FDA principal deputy commissioner and chief scientist. He plans to join the agency in May.

The principal deputy commissioner's job gives Torti the delegable authority of FDA commissioner. As the agency's chief scientist, Torti will oversee the agency's intramural research program, launch a fellowship program, and construct a post-approval surveillance programs. The job was created under the FDA Amendments Act of 2007

To accept the political appointment, Torti, who specializes in genitourinary cancers, is taking a leave of absence from his job as director of the Comprehensive Cancer Center at Wake Forest University School of Medicine, the Winston-Salem Journal reported. **Jerry Garvin**, a pathologist, will serve as the center's acting director.

Torti serves on the NIH National Advisory Council for Complementary and Alternative Medicine. He also founded and serves as President of the Cancer Biology Training Consortium, a national society of cancer biology department chairs and program directors.

ROSWELL PARK CANCER INSTITUTE opened its $2.6 million Clinical Research Center, which will provide the foundation for the Institute's expanding phase I and drug development clinical research. Housed on the seventh floor of the Roswell Park hospital, the center was built with a $2

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NCI Goal To Cut Trial Activation Time In Half, Doroshow Says

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even those familiar with the clinical trials process, Doroshow said to the NCI Board of Scientific Advisors. "There are an enormous number of loops—some that have no end," he said.

"When you add the cooperative group process to the cancer centers process, 800 days to another 200 days, you are talking about a length of time greater than the entire Kennedy Administration to open a trial to the first patient."

As a result of the Vanderbilt study, NCI Director John Niederhuber has established a goal to cut the trial activation time in half, Doroshow said.

"We really can't compete internationally if we have a system that requires 1,000 days to get a trial up and running," Doroshow said to the BSA at its meeting March 3.

The study, which counted every step taken at NCI, two cooperative groups, and four cancer centers, was conducted by David Dilts and Alan Sandler, co-directors of the Center for Management Research in Healthcare at Vanderbilt. Dilts is also director of the Engineering Management Program in the School of Engineering. Sandler is an associate professor of medicine in the Division of Hematology/Oncology and medical director of the Thoracic Oncology Program.

The two cooperative groups that participated in the study were the Cancer and Leukemia Group B and the Eastern Cooperative Oncology Group. The four cancer centers were Vanderbilt-Ingram, UNC Lineberger, Ohio State University, and Fox Chase Cancer Center.

The four centers were chosen on the advice of the NCI Cancer Centers Program for how well they scored well in peer review on their clinical trials process.

Even investigator-initiated trials at cancer centers take a median of 116 to 252 days, with a range of 21 to 836 days.

As an example, Sandler provided data on the activation of his own trial, E1301, a study of chemotherapy for advanced non-small cell lung cancer. "There is plenty of guilt to pass around to everyone," Doroshow said. "The trial sat on Alan's desk for six months. It sat in the ECOG office for over a year. It sat in [the NCI Cancer Therapy Evaluation Program] for nine months. It was four months in the Central IRB—for a grand total of 975 days before the trial was open for accrual."

Some phase III trials take well over 1,000 days from concept receipt to activation, the Vanderbilt research found. "How can any study be relevant that has to take three years before a single patient is entered?" Doroshow said.

The researchers also looked at patient accrual at the cancer centers. About 20 to 30 percent of trials accrue no patients, while about 30 percent of trials accrue one to four patients.

"Even if you exclude rare tumors, somewhere between 50 to 60 percent of trials opened in these august cancer centers accrue less than five patients," Doroshow said. "And roughly a quarter accrue zero patients. NCI is giving each center money to run a clinical trials office, a quarter of which is completely useless in terms of accrual."

The study also looked at the time to accrual for 15 ECOG phase III trials. If it took less than the median time to open a study, the trial could meet its accrual goal. But trials that were in the system for more than 800 days rarely completed accrual.

"If you took in excess of the median, the trials never finish, they never complete accrual—they are a waste of money," Doroshow said.

"Just Say No" To Trials

Dilts and Sandler made several initial recommendations based on the study:

—Data should be collected and analyzed at each cancer center.

—The cooperative groups and NCI should "just say no" to starting too many studies.

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Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information: www.cancerletter.com

"One of our cooperative groups annually works on 70 to 80 new trials a year, year in and year out," Doroshow said. "They open between 15 and 20 trials a year. So if they stop today, they have enough trials for the next four years. They don't have to work on any new trials. They are trying to squeeze 70 trials through an output that will only produce 20 trials. This leads to an enormous amount of useless throughput that never gets done."

—Stop "tweaking" studies.

"One of the biggest problems is that it must be a genetic urge for investigators to tweak their trials," Doroshow said. "There are numerous examples where studies were all the way through, when the Central IRB asked for one change, and the investigator could not help himself or herself—it's taken three years to get to the Central IRB, there must be something new they can add to the study. That means the study has to go all the way back to the beginning. It's just like Chutes and Ladders [the classic children's board game]. You go all the way back to the beginning and start all over again."

The researchers also conducted a simulation to show how making changes to the system would improve the results.

"If you doubled the budget of one of the cooperative groups, would it change the mean time for the study? There would be minimal change, because there are so many other things," Doroshow said. "Adding more people doesn't do the job because the system is interrelated."

"If we improved review times, if told CTEP you have to do things twice as fast, that would only produce about a 15 percent improvement," he said. However, if you improve performance at a cooperative group as well as at CTEP, "you can simulate a system that is much more nimble.

"It is clear that this is a system-wide problem that is going to require major changes across the board," Doroshow said. "How do we re-engineer a 50-year old system to have an output that is nimble?

"One thing we clearly have to do is not develop protocols as if they were built to order," but to use standard elements, Doroshow said. "If it were a car you were building, you would get a De Lorean and it would cost a fortune, rather than building a Toyota that has standardized parts, that gets done. We really have to understand how to do this."

Dilts and Sandler also suggested forming teams of investigators to develop phase III trials over a short amount of time. "We would lock them in the Bethesda Hilton for three days," Doroshow said.

The NCI Clinical Trials Advisory Committee is forming a working group to look at the recommendations, and a study of the NCI intramural clinical trials program also is underway, Doroshow said.

Capitol Hill:

Grassley Presses Amgen For Aranesp "Bundling" Data

By Paul Goldberg

Sen. Chuck Grassley (R-Iowa) asked Amgen Inc. to account for rebates to some physician groups for purchasing the erythropoiesis-stimulating agent Aranesp.

In a letter dated April 3 and addressed to Amgen CEO, president and chairman Kevin Sharer, Grassley describes data he obtained through an earlier inquiry and requests additional information about Amgen's drug rebate and discount calculations.

"The information raises questions," he said in a statement. "Some oncology practices in some states are receiving unusually high rebates for purchasing Aranesp. These trends underscore the need for greater transparency in the financial relationships between drug makers and doctors. Patients deserve to know what's going on as they make decisions about their health and safety based on the advice of their doctors."

Grassley's questions are part of an effort by lawmakers to delve into the practice of "bundling," which involves giving deeper discounts on the white blood cell growth factors Neulasta and Neupogen to practices that use larger amounts of Aranesp.

The inquiries are aimed to bring out the details of the companies' supply contracts with physicians that made ESAs the single largest product in oncology, which generated $4.85 billion in sales in 2006. Utilization of these agents has dropped by about half amid safety concerns in 2007, and FDA is considering placing additional restrictions on their use.

Last week, a letter from the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce has similarly requested information on Amgen's reliance on bundling.

The House subcommittee has scheduled a hearing May 8 to examine direct to consumer advertising of drugs that include Aranesp and Johnson & Johnson's ESA Procrit. Though Amgen hasn't relied on DTC advertising to sell Aranesp, it does market Neulasta and Nupogen directly to patients. The bundling arrangement then gives physicians the incentive to offer these patients Aranesp after they receive treatment.

Last year Grassley sought to increase access by the Food and Drug Administration to drug study results for anti-anemia drugs. Last month, an FDA advisory committee recommended more limited use of anti-anemia drugs due to safety concerns.

The text of the letter follows:

Dear Mr. Sharer:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs and ensure that taxpayer and beneficiary dollars are appropriately spent on safe and effective drugs and devices.

Last May, I wrote to you regarding a New York Times article that doctors were profiting through rebates they received from purchasing erythropoiesis-stimulating agents directly from Amgen, Inc. and then collecting payments from Medicare and private insurers, often above the price they paid for the drugs.

Three weeks ago, during the Oncologic Drugs Advisory Committee discussion of the safety of ESAs, the panelists raised concerns that ESAs may be doing more harm than good in patients with certain cancer types and questioned whether or not Amgen's practice of discounting the price of its drugs for doctors who buy large quantities of ESAs may be encouraging overuse of these drugs.

As part of the Committee's inquiry into the potential impact of pricing practices on the utilization of ESAs, I sent a letter in August requesting that Amgen provide information regarding rebate payments/discounts to physicians, group practices, and others who purchased Aranesp and/or Epogen.

A review of the information provided by Amgen raises some questions regarding the rebate arrangements between Amgen and physicians/group practices.

According to Amgen, almost $800 million in rebates were paid in calendar 2006 to more than 6000 facilities, including group practices, hospital inpatient and outpatient departments, home health agencies and skilled nursing facilities. About 80 percent of that total went to physicians, group practices, and physician clinics. In addition, with the exception of three states, the total amount of rebates paid to facilities in each state increased each year from calendar year 2004 through calendar year 2006, in some cases doubling in total amount.

For example, about 90 facilities in Alabama received about $7 million in total amount of rebates for Aranesp in calendar year 2004. That amount increased to more than $17 million to about 100 facilities in calendar year 2006-an increase of about $10 million. Similarly, the total amount in rebates paid to facilities in South Carolina almost doubled from more than $7.5 million to about 70 facilities in calendar year 2004 to more than $14.5 million to about 80 facilities in calendar year 2006.

When one examines the five group practices/physician clinics that received the most rebates from Amgen during calendar years 2004-2006 in a specific state, some of the payments to the same group practices also increased over time. For example, in Alabama the rebates to one cancer center more than doubled over the three-year period from $1.3 million in calendar year 2004 to almost $2 million in calendar year 2005 to more than $3 million in calendar year 2006. Based on information provided on the center's Website, there are about 10 oncologists on staff, which translates to about $300,000 in rebates per oncologist in calendar year 2006.

In Indiana, more than $15 million in rebates were paid to about 220 facilities in calendar year 2004, more than $27 million in 2005, and more than $34 million in 2006. Rebates to one 5-physician practice increased from more than $500,000 in calendar year 2004 to almost $1.3 million in calendar year 2006. Rebates to another group practice increased more than fourfold from about $1.5 million in calendar year 2004 to about $6.5 million in calendar year 2006.

According to that practice's Website, there are about 10 oncologists on staff, which translates to about $650,000 in rebates per oncologist in calendar year 2006.

I have cited only a few examples in this letter, but based on the information submitted by Amgen, it seems that group practices/physician clinics in some states are receiving significant amounts of rebates for purchasing Aranesp.

To understand what accounts for these rebate totals, I would appreciate a discussion of the factors that are considered in determining the rebates/discounts Amgen pays to physicians, group practices, and physician clinics. For example, do the rebates/discounts take into account the purchase of another drug and/or other product(s) from Amgen or are rebates related to amounts purchased in certain time frames?

Please also describe any factors specific to individual states that may impact Amgen's rebate/discount calculations.

NCI Plans SBIR "Bridge" Grant To Commercialize Technology

By Kirsten Boyd Goldberg

NCI plans to establish a new grant program that would provide $10 million a year to small business emphasizing biomedical technology commercialization.

Under the Congressionally-mandated Small Business Innovation Research program, NCI must provide a portion of its research project grants budget to small businesses. This year, the SBIR set-aside of NCI funding is $104 million. Funding for the new grants would come from the SBIR set-aside for FY 2009 and would be awarded this December.

NCI's new SBIR Phase IIB Bridge Award Pilot Program would focus funds on commercially viable technologies. Within the SBIR program, it would serve as a step between Phase II and Phase III funding. The concept is modeled on the National Science Foundation's Phase IIB Option and has the same key feature, requiring the applicant, a company, to raise matching funds from investors or partners.

NCI officials presented a concept statement for the new program as an "informational" item to the NCI Board of Scientific Advisors at its March 3 meeting. The board was not asked to vote on it.

The board voted unanimously to approve concepts for new grants in smoking cessation and smokeless tobacco use, as well as renewal of the Pediatric Brain Tumor Consortium. The board also voted 20-3 to defer a concept that proposed to establish a radiation therapy research program on cancer disparities. The board formed a subcommittee to rewrite the proposal.

Excerpts from the text of the concept statements follow:

SBIR Phase IIB Bridge Award Pilot Program. Concept for a new RFA, cooperative agreement, first year set-aside $10 million, five to 10 awards in year 1, length of award three years, estimated total cost $30 million. Program director: Michael Weingarten, SBIR Development Center, Office of the Director.

The purpose of the Phase IIB Bridge Award is to extend the R&D efforts beyond a current Phase II SBIR grant or contract to accelerate the Phase II project toward commercialization and/or significantly enhance the project's commercial viability. To this end, budgets up to $1 million in total costs per year and time periods up to three years may be requested for the Phase IIB Bridge Award. These funding levels are based on estimates obtained from NCI's Developmental Therapeutics Program regarding the amount of funds required to complete pre-clinical development for new therapeutics. For example, it is estimated that preclinical drug development costs range from $1-3 million (i.e., small molecules), and $1-6 million (i.e., biologics).

Most importantly, however, this funding opportunity is intended as a pilot initiative to evaluate a new strategy to facilitate partnerships between NCI's SBIR awardees and third party investors and/or strategic partners. Specifically, the Phase IIB Bridge Award will only provide funds to SBIR Phase II awardees that are able to raise matching funds from third party investors. Because NCI will be sharing in the investment risk, this will incentivize private sector investors to fund these projects.

Successful applications must demonstrate significant commercial potential and a clear commercial path forward. Applications must also show a clear advantage over competing technologies and should demonstrate significant progress during the Phase II SBIR activity. Applicants will be encouraged to forge partnerships with investors and strategic partners that have significant prior experience in commercializing emerging cancer technologies. These critical partnerships will enable the NCI to leverage the due diligence process of business investors in the private sector, thereby increasing the chance of commercial success.

Under this solicitation, applicants will be required to obtain third party funds that match the NCI award on a minimum one-to-one basis. The matching funds requirement will ensure that the third party (or parties) will assume a level of financial risk that is equal to or greater than the federal government's risk in supporting the continuation of the selected projects. However, the expectation is that this initiative will foster new business partnerships in which many of these third parties will provide significant levels of downstream financing beyond the initial matching funds in order to drive promising technologies toward the marketplace.

Only third party, non-federal funds will satisfy the matching requirement. It will be the sole responsibility of the small business concern to negotiate the terms of the third party investment. A third party investor may include, but is not necessarily limited to, another company, a venture capital firm, an individual "angel" investor, a non-profit organization (e.g., foundation), a state or local government, or any combination of the above. A third party investor may not include owners of the small business, their family members, and/or "affiliates" of the small business. Third party matching funds may include cash, liquid assets, or convertible debt. However, in-kind support, intangible assets, and self funding will not be acceptable. Investment deals and/or partnership arrangements that are not specifically addressed by these guidelines will be evaluated on a case-by-case basis.

At the time of application, the third party investors and/or strategic partners will be required to provide a non-binding term sheet outlining the terms of the proposed investment. Following the review of applications, a small business concern that is selected for a Phase IIB Bridge Award must provide to the NIH an updated term sheet naming all investors and all

sources of third party funds needed to satisfy the matching requirement over the lifetime of the award. NIH funds will only be disbursed after the small business concern has received funds from the third party investors. The third party investment may be "traunched" (i.e., disbursed in multiple payments), as negotiated between the small business and the investors. However, at no time shall the amount of NIH funds disbursed under the Phase IIB award exceed the amount of funds provided to the small business by the third party investors. The matching requirement will leverage the Phase IIB Bridge Award to assist small businesses in attracting up to $3 million in third party funding, and potentially more private sector funding at the discretion of the investors.

The SBIR Phase IIB Bridge Award application should represent a continuation of support for R&D that extends previous work funded by an original Phase II award. It is expected that the achievement of significant milestones, supported by a previous SBIR II award (grant or contract), will indicate the merit and need for further R&D. The previously funded Phase II award need not have been funded in response to any particular NIH SBIR solicitation. However, the Phase IIB Bridge Award application must fall within the technical scope of this funding opportunity announcement.

The Phase IIB Bridge Award will be open to all current Phase II SBIR awardees and past Phase II SBIR awardees that began their Phase II award within 5 years of the Phase IIB application receipt date. Only one Phase IIB Bridge Award will be made for a single Phase II SBIR project. To participate in the Phase IIB program, the small business concern must have completed at least one year of work on the Phase II grant or obtain special permission from the NCI project manager. Both grantees and contractors will be eligible.

The Phase IIB Bridge Award will be supported as a continuation of the Phase II award under the U44 (SBIR cooperative agreement) mechanism. The current RFA will be issued once with two receipt dates. The current plan is to set aside $10 million in FY09 funds from NCI's SBIR set aside budget. Each award will provide up to $1 million per year in total costs for up to three years, for a maximum of $3 million in additional support (NCI dollars). It is expected that 5-10 grants will be awarded in FY 2009. Thus, the total cost of the current RFA is estimated at $30 million (10 awards x $3 million over three years). Set aside funds that are unused for Phase IIB Bridge Award grants in FY09 will be returned to the general SBIR pool to fund more Phase I and Phase II grants.

The technical scope of this RFA includes the R&D of cancer therapeutics and cancer imaging technologies. This funding opportunity is specifically intended to help small businesses address key regulatory approval milestones to attract downstream investments and strategic partnerships, thereby accelerating these projects toward commercialization. Activities supported a Phase IIB Bridge Award may include an extension and expansion of preclinical R&D, clinical evaluation, and/or other activities needed to meet the requirements and expectations of the FDA.

Projects in the NCI SBIR portfolio that are expected to benefit immediately from the Phase IIB Bridge Award are in the following areas: drugs (small molecules), biologics, vaccines, radioligands, medical devices for cancer imaging, imaging agents, and image-guided interventions (including image-guided drug delivery systems).

Increasing smoking cessation in low income adult populations. Concept for a new RFA, first-year set-aside $3.5 million, eight to 10 awards, five years, estimated total cost $14-17 million. Program director: Erik Auguston, Division of Cancer Control and Population Sciences.

There are a number of well-established findings related to elevated smoking among low income populations. For example, low income populations are more likely to start smoking at an earlier age. They make fewer attempts to quit and experience less success when attempts are made. In addition, they report more obstacles to seeking and engaging in treatment and are les likely to receive cessation support from healthcare providers. They also have less protection from smoking bans and restrictions. Despite a fairly solid knowledge base regarding factors that contribute to elevated smoking in this population, little research has been performed regarding cessation. A recent search in PubMed revealed 139 studies related to smoking and low income populations. However, the vast majority of these, approximately 98 percent, were observational studies.

The limited intervention research that has been performed in low income populations suggest that modified and novel approaches hold promise. A recent study of African American women living in public housing developed a multi-element intervention that provided nicotine replacement therapy and was culturally modified to include counseling that focused on empowerment, self-efficacy, and building social support. The investigators found that reported changes in social support and self-efficacy were predictive of six-month abstinence. Similarly, an NCI-funded project by Ahluwalia and colleagues working with low income African Americans who were light smokers found that providing direct information and advice-based counseling had a larger impact in cessation than the effect associated with using nicotine replacement therapy. Although suggestive, these results illustrate the value of research that more fully explores possible treatment approaches. Given the very limited available literature, how best to increase successful smoking cessation in low income smokers is not known.

The purpose of this RFA [concept] is to stimulate intervention research to develop a strong evidence base on how to dramatically increase quit rates among low income adults. The long-term goal is to facilitate a significant reduction in smoking prevalence among low income adults, thereby reducing the excess disease burden of tobacco use within these groups and decreasing the smoking prevalence in the U.S. It is anticipated that applications responding to this RFA would attempt to directly address smoking cessation in this population via targeted individual, systems, or population-

based treatment approaches. All applications should include a strong rationale for why the proposed approach is specifically relevant to the population of interest. This concept is not intended to support animal research or observational human studies.

Potential research questions to be addressed include:

—What novel treatment approaches may be developed that will increase cessation among low income smokers?

—In what ways might individual, quit-line, and/or heath care system-based treatments of tobacco dependence be personalized for low income smokers to enhance treatment effectiveness?

—What modifications to existing treatments can overcome barriers to low income smoker participation?

—How can social (e.g. social networks, social ties, discrimination, historical factors) and other contextual (e.g. culture, tobacco control policies) factors known to affect smoking in low income adults be addressed in order to enhance smoking cessation treatment success?

About eight to 10 grants would be funded via R01 and R21 mechanisms. A maximum of $3.5 million (direct and indirect costs) per year for five years will be requested for a total investment of $14 million to $17 million depending on the distribution of R01 versus R21 grants.

Measures and determinants of smokeless tobacco use prevention and cessation. Concept for a new RFA, first year set-aside $2.5 million, eight to 10 awards, four years, total estimated cost $8 to $10 million. Program director: Mark Parascandola, DCCPS.

The purpose of this RFA [concept] is to build a strong science base around smokeless tobacco use, particularly focused on measure and determinants of smokeless tobacco use prevention and cessation. This RFA would fund laboratory, clinical, and population-based research, with a focus on developing new methods for measuring smokes tobacco use and studying determinants of smokeless tobacco use, initiation and cessation. Funded investigators would represent a variety of disciplines in the basic, behavioral, and clinical sciences, including epidemiology, psychology, biology, and chemistry. A better understanding of the factors that lead to differences in smokeless tobacco prevalence between groups is essential for conducting effective smokes tobacco prevention and control efforts, which will ultimately reduce death and disease associated with tobacco use.

It is expected that applications responding to this RFA will study smokeless tobacco products and their use in human subjects. While it is expected that applicants will emphasize observational studies, intervention studies may be considered if they are demonstrably innovative and focused on specific populations. The RFA may support studies that identify targets for population-based intervention by testing explanatory models of smokeless tobacco marketing and use.

While the focus of this RFA is on smokeless tobacco use in the U.S., applications that propose to conduct international studies are also appropriate if they have relevance to understanding patterns of smokeless tobacco use in the U.S. To effectively address the key research questions around smokeless tobacco use, scientists from a variety of disciplines should be engaged. Potential research questions to be addressed include:

—What is the overall public health impact of ST use?

—What are the key determinants of initiative and use among high risk groups?

—What are the best measures for smokeless tobacco use behavior and exposure?

—What are the characteristics of the range of smokeless tobacco products in current use and how do the use of these products impact users' behavior?

—How do the design, content, and other characteristics of smokeless tobacco products affect behavior?

—How does ST use interact with other forms of tobacco use among dual users of smokeless tobacco and other tobacco products?

—To what extent does ST act as a gateway to cigarette smoking?

—How does marketing of new ST products impact prevalence of tobacco use, including initiation and cessation of cigarette smoking?

Because the data are very limited for some of the key research questions, this RFA will use both the developmental R21 mechanism as well as the R01 mechanism.

Pediatric Brain Tumor Consortium. Reissue of an RFA, cooperative agreement, one award for five years, total $10.8 million. Program director: Malcolm Smith, Cancer Therapy Evaluation Program, DCTD.

This concept proposal is intended to continue support for the PBTC, which was funded initially April 1, 1999. The consortium was conceived as a dedicated clinical trials organization able to translate innovative therapies from the laboratory to early phase clinical testing so that treatment for primary brain tumors in children can be improved. The PBTC has filled a unique niche in the NIH pediatric brain tumor research portfolio through its ability to translate multiple innovative therapies from the laboratory to the early phase clinical research setting.

Thirteen therapeutic studies have been approved by CTEP during the PBTC's second grant funding period. Nine clinical trials have been completed during the second funding period. Average accrual to consortium therapeutic studies has been 135 patients per grant year for years 6-8, with accrual for grant year 9 on track to meet that number. The results of 10 completed PBTC trials have been published or submitted for publication.

The PBTC has a good working relationship with the Children's Oncology Group and its Brain Tumor Committee to ensure that results from the PBTC's phase I and II trials can be confirmed through additional phase II and multi-agent phase III clinical trials in COG. Several anti-angiogenic agents studied in phase I trials by the PBTC are moving to COG for further study:

—Cilengitide is nearing final COG approval as a phase II study in CNS tumors following the phase I trial in PBTC.

—Lenalidomide is close to completion in PBTC and is under consideration for a phase II study in low grade gliomas in COG.

—The PBTC phase II trial in bevacizumab and irinotecan is under consideration as a post-irradiation arm for newly diagnosed malignant gliomas in COG.

In the Cancer Centers:

Varshavsky Wins Gotham Prize; Carol Receives Sohn Prize

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million dollar gift from an anonymous benefactor and additional funds provided by RPCI. The gift will support capital and operational expenses for the center's first two years. Once fully operational, it is estimated that about half of the expense to run the center will be recouped from grants and contracts. The center includes seven inpatient beds and 10 outpatient treatment chairs, a staff of research nurses, an Investigational Drug Service staffed by clinical pharmacists and pharmacy technicians specializing in study-related drugs and agents, a specimen processing area, a conference room for staff, and a conference room for patient and family education and counseling. . . . **ALEXANDER VARSHAVSKY**, the Smits Professor of Cell Biology at California Institute of Technology, was selected the first winner of the $1 million Gotham Prize for Cancer Research for his idea of a new approach to treatment of cancer that takes advantage of unique changes in the DNA of cancer cells. **Mark Carol**, a neurosurgeon and entrepreneur involved in various health-related companies, was named recipient of the $250,000 Ira Sohn Conference Foundation Prize in Pediatric Oncology for his idea focused on novel approaches for using radiation therapy to treat patients with cancer. The Gotham Prize was begun in 2007 by hedge fund managers **Joel Greenblatt** and **Robert Goldstein** of private investment firm Gotham Capital, and medical researcher **Gary Curhan** of Harvard Medical School, with support from the Ira Sohn Research Conference Foundation and **Ephraim Gildor** of Axiom Investment Advisors. . . . **MONICA MORROW** joined Memorial Sloan-Kettering Cancer Center as chief of the Breast Service in the Department of Surgery. Morrow is also the incumbent of the Anne Burnett Windfohr Chair of Clinical Oncology, effective January 2009. Morrow was chairman of surgical oncology at Fox Chase Cancer Center where she held the G. Willing "Wing" Pepper Chair in Cancer Research. . . . **LOMBARDI COMPREHENSIVE CANCER CENTER** Director **Louis Weiner** announced two new leadership appointments. **Eliot Rosen** will serve as co-leader of the Radiation Biology & DNA Repair program. **C. Richard Schlegel** will serve as co-leader Growth Regulation of Cancer program. Rosen holds the Gragnani Chair in Oncology and Radiation Biology and Schlegel is chairman of the Department of Pathology. . . . **MERVIN YODER** was appointed director of the Herman B. Wells Center for Pediatric Research at Indiana University School of Medicine and Riley Hospital for Children. Yoder is the Richard and Pauline Klingler Professor of Pediatrics at the IU School of Medicine and member of the Indiana University Melvin and Bren Simon Cancer Center. Yoder succeeds **Mary Dinauer**, the Nora Letzter Professor of Pediatrics and professor of microbiology and immunology and of medical and molecular genetics, who was director of the Wells Center since 2000. Dinauer will continue her research in gene therapy. . . . **WILLIAM CANCE**, chairman of the University of Florida department of surgery, became president of the Society of Surgical Oncologists at the society's annual business meeting in March. Cance said his primary goal as president is to reach out to surgical oncologists, both nationally and internationally, to foster more collaboration. SSO has more than 2,000 members. Cance also serves on the NCI Board of Scientific Counselors. . . . **FEINSTEIN INSTITUTE** for Medical Research signed a collaborative agreement with the Karolinska Institutet in Sweden. The agreement paves the way for Karolinska graduates to conduct post-doctoral research in New York and scientists from The Feinstein to study at the Karolinska's laboratories in Stockholm. The graduate students at the Karolinska and The Feinstein are medical doctors who have gone on to obtain a doctoral degree in research. The collaboration will mean that as many as half a dozen scientists may be able to study abroad and that Feinstein scientists can host an equal number of Karolinska's post-doctoral students. They will still have to apply for a seat in the lab, and a joint admissions committee from both institutes will review the applications and make the selections. . . . **DALE ADAMS** joined City of Hope as vice president and chief pharmacy officer, where he will oversee all pharmacy services as well as radiation oncology services. Also, he will oversee programs to ensure medication safety, manage medication supplies. and work collaboratively with physicians choosing appropriate patient drug therapies. Adams was vice president of medical services at Long Beach Memorial Medical Center and Miller Children's Hospital in Long Beach, Calif.

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The Cancer Letter
PO Box 9905
Washington DC 20016
Tel: 202-362-1809
www.cancerletter.com