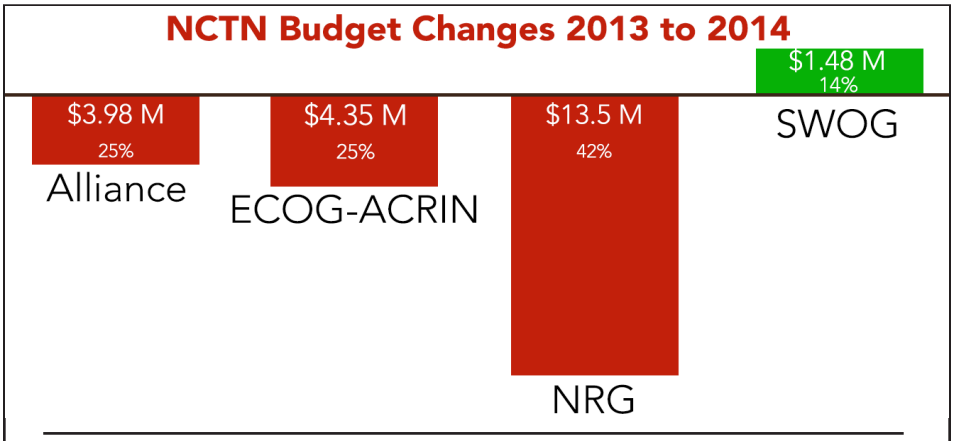
THE CANCER LETTER

May 16, 2014 • www.cancerletter.com • Vol. 40 No. 20



Over $20 Million Carved Out
From Statistical, Operations Centers

By Paul Goldberg

The budgets of operations and statistical centers of adult clinical trials groups were cut by about $20.4 million, group chairs say.

The cuts make it difficult for the groups to continue to support ongoing trials and raise questions about the prospects for starting a new generation of trials.

NCI officials say that, overall, the budget for the groups is staying flat, in part because some of the money is being channeled into 30 sites that received the Lead Academic Participating Site designation.

LAPS, which are run by cancer centers, will be allowed to charge more for putting patients on studies.

So where are the cuts?

(Continued to page 2)

No Justification Provided

AAUP Demands Reinstatement of Faculty Denied Tenure Renewal at MD Anderson

By Matthew Bin Han Ong

The American Association of University Professors sent a letter to Ronald DePinho, president of MD Anderson Cancer Center, urging the reinstatement of two faculty members who were denied tenure renewal without stated reasons.

The letter is a part of AAUP's response to a request for an investigation, which was triggered by the administration's refusal to provide justification for denying tenure renewals to faculty who received unanimous votes for renewal from the Faculty Senate Promotions & Tenure Committee (The Cancer Letter, April 25).

(Continued to page 10)

Data: Deep Cuts in Ops and Stats; NCI: Overall Spending Stays Flat

(Continued from page 1)

Comparisons between 2013 and 2014 are complicated, because the adult groups were consolidated before the funding decisions were made, and the effort requires sifting through thousands of pages of grant documents, both old and new.

Three of the four adult groups went through this exercise together, using the same template.

Here is what they found:

• The operations budget of NRG Oncology has been cut by 51 percent. NRG is the entity that was formed through the merger of the National Surgical Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group and Gynecologic Oncology Group.

• The NRG statistical center got a 27 percent cut.

• The Alliance for Clinical Trials in Oncology operations budget was cut by 35 percent. The group was formed through the merger of Cancer and Leukemia Group B, the North Central Cancer Treatment Group, and the American College of Surgeons Oncology Group.

• The ECOG-ACRIN operations budget got a 30 percent cut. The group was formed through the merger of Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network.

NCI officials declined to comment on the financial data contained on slides that were forwarded to them by The Cancer Letter.

"These are not slides that NCI created, and we have not received them from anyone other than TCL," said Peter Garrett, NCI acting director of communications.

"We are speaking with the group chairs individually about their awards, and meeting with each of the chairs and their key financial and statistical staff to discuss their specific concerns. Therefore, it's premature for us to speak publicly about budget details."

However, some believe that public airing of the issues would be the right thing to do.

"It is clear that we are in a situation now where things have been set in motion that will harm the system and impact both the science and patient outcomes," said Michael Katz, a patient advocate who has worked with ECOG-ACRIN who recently brought together an ad hoc group of advocates who are seeking more public discussion (The Cancer Letter, May 2).

"It's too late to prevent that," said Katz after reviewing the data compiled by group chairs. It's our job now to all pull together and understand the implications of what's been done and work through our collective actions to minimize the damage."

The American Cancer Society and the American Society of Clinical Oncology are watching the situation as well.

"It is imperative that we have a vital clinical trials program," said Otis Brawley, ACS chief medical and scientific officer. "The NCI clinical trials program has been a very positive force in oncologic care. There is data to show that participation improves a doctors' quality of practice for all his or her patients. For many cancer patients it is an opportunity and often the only opportunity to participate in research and receive cutting edge treatment."

ASCO, too, urged that the matter be resolved. "ASCO and its members are frustrated by the financial and budgetary challenges we are facing and we look forward to working collaboratively with the NCI and all members of the cancer research community to identify and implement potential solutions," the society said in a statement.

Cuts Spread Unevenly

At a glance, the cuts aren't evenly spread between groups.

"I am fully supportive of the enhanced per-case reimbursement going to the LAPS, but it can't be done at the expense of the support for the operations centers that develop and execute the trials," said Walter Curran, one of the chairs of NRG and director of Winship Cancer Institute of Emory University.

"When you have three groups come together partially for economy of scale, we should be able to run the same programs at something less than 100 percent of the prior funding. Particularly in year one, we are not

Editor & Publisher: Paul Goldberg
Associate Editor: Conor Hale
Reporter: Matthew Bin Han Ong

Editorial, Subscriptions and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
General Information: www.cancerletter.com

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

2014 NCTN Budget Analysis - CTEP

	Alliance	ECOG -ACRIN	NRG
treatment trials in accrual	38	36	52
>500 accrual target	10	7	8
>1000 accrual target	5	2	6
treatment trials in devel	9	5	12
>500 accrual target	0	1	2
>1000 accrual target	0	0	1
molecular screening trials	1	1	0
screening accrual target	8000	3000	
Projected accrual 2014	3120	3150	5026

2014 NCTN Budget Analysis - CTEP

	Alliance	ECOG-ACRIN	SWOG	NRG
2013 ops	8,642,694	10,155,596	5,951,652	19,856,569
2014 op	5,653,875	7,127,766	5,701,766	9,731,059
ratio	0.65	0.70		0.49
2013 SDC	7,548,379	7,407,237	4,606,846	12,401,717
2014 SDC	6,549,716	6,078,304	6,340,997	9,003,057
ratio	0.87	0.82		0.73
total cut	$3,987,482	$4,356,763	+$1,484,265	$13,524,170

Net decrease: $20,384,150

Source: NCTN Adult Group Chairs

going to be having a 50 percent cost reduction. It might be in the 10 to 20 percent range.

"It's like starving your mission control center in any kind of operation. It's just very unwise. You don't have a network if you don't have a well-positioned network center."

Consolidation may have brought about some economies of scale, but a 50-percent reduction is excessive, he said. "It might be in the 10 to 20 percent range," Curran said.

The groups have been given ample time to prepare, NCI's Garrett said.

"As we have said publicly, the NCTN budget for Fiscal Year 2014 is $151 million, which is the same as the funding for the cooperative groups in previous years despite widespread budget reductions across NCI programs," he said. "NCI has anticipated that it would be a challenge for the long-standing cooperative groups to combine and/or consolidate, so over the preceding years of the NCTN competition for funds, we have provided transition funds to support consolidation efforts.

"Dr. Jeff Abrams [NCI acting director for clinical research], when speaking with the advocacy community, also mentioned that NCI recognizes that this budget is going to require difficult decisions on the part of the leadership of the groups and that is why NCI is meeting with them to identify areas where both NCI and the groups can be flexible."

In the new NCI National Clinical Trials Network, funding is determined by the number of patients enrolled on trials, group chairs say.

For example, total cut for NRG was $13.5 million, while SWOG, a group that didn't go through a merger, received nearly a $1.5 million raise.

However, groups can't necessarily improve their funding since overall accrual is capped by NCI.

The new clinical trials system appears to have many moving parts, some of which aren't yet publicly understood, and many of which are likely to receive public—and, possibly, congressional—scrutiny.

Some events have yet to play out:

• The Children's Oncology Group hasn't been public about its funding, though insiders say that the group has experienced cuts and its leadership is in the midst of discussions with NCI.

• Not all the LAPS awards have been received and analyzed, but several leaders of LAPS said to The Cancer Letter that they are concerned about their prospects of meeting accrual targets since the number of trials is expected to drop. This is important, because cancer centers are a politically powerful constituency.

"The financial and programmatic elements of the accrual-based funding algorithm of the new NCTN were poorly planned and abruptly implemented without adequate transition planning," ECOG-ACRIN co-chairs Robert Comis and Mitchell Schnall said in a statement. "Although the new NCTN announcements come with promises of a vastly improved system, these actions have far-reaching implications that threaten the continued viability of a publically funded clinical trials program."

Monica Bertagnolli, chair of Alliance, said she is similarly puzzled.

"The NCTN now has a cap on accrual of 17,000 patients per year, with only 12,000 allocated to adult patients," Bertagnolli said to The Cancer Letter. "There was no phase-in period for this accrual reduction, and for the studies currently in the Alliance portfolio, we will exceed our allocated numbers if accrual proceeds as projected.

"Do we respond to these pressures by closing current studies so that we can open new ones?

"Do we put a hold on all new studies? For how long? We also experienced a major reduction in our operations budget, which is linked to number of accruals. This leads to more difficult choices.

"Should we prioritize new studies based upon having at least one study for each disease, or according to which studies have the highest potential impact, or give consideration only to studies that are the right size to fit our accrual cap and operations funding?

"How do we motivate our scientific leaders to continue their volunteer work to develop new trials when it is clear that the system cannot accept the great majority of these studies? How can we continue to ask our member institutions to open trials when accrual capacity fluctuates but their costs of operation remain fixed? These are just a few of the questions raised by our researchers.

Even SWOG, which received a small raise, is making changes.

"We have of course met with the NCI, preliminarily with our foundation board, and convened a group of executive leadership to discuss 2014-15, and longer, planning," said Charles Blanke, SWOG chair and professor of medicine at Oregon Health and Science University's Knight Cancer Institute. "We have also put a real-time accrual monitoring plan into place.

"We do not at this time anticipate closing trials because of budget. We may need to decrease travel and slow hiring for administrative positions. The latter could slow activation of new studies."

NCI: NCTN Makes "Amazing Trials" Possible

"It is important to note that the $151 million does not capture the many other functions that NCI provides in support of the NCTN and the entire clinical trials enterprise," Garrett said. "A few of these key centralized functions include the Cancer Trials Support Unit (CTSU), a 'one-stop shop' for the groups to access all trials, a Central Institutional Review Board (CIRB) to eliminate the need for local IRB approvals, tumor banking for each group, and ancillary studies funded to support biomarker and quality of life research.

"As Dr. [James] Doroshow [director of the NCI Division of Cancer Treatment and Diagnosis] stated on the teleconference with the advocacy community , with the resources available, the network is going to be able to do some really amazing trials, things that couldn't even have been conceived possible when the Clinical Trials Working Group started.

"Another important outcome of this new network will be the ability to facilitate the conduct of trials in rare tumors where patient accrual has always been very difficult. The availability of a national network of clinical trials sites to locate and enroll patients with unusual cancers should enhance the feasibility of conducting such studies. Also, as more cancers are molecularly defined and classified into smaller subsets, the new network structure will support the molecular screening studies needed to define and locate the smaller groups of patients who might be eligible for such studies," Garrett said.

The institute with work with the chairs of each trial group "to ensure active trials that are accruing appropriately and meeting endpoints are not closed, so no current patients would be dropped from any existing trials," Varmus said. "As Dr. Varmus mentioned in his open letter, NCI remains committed to every patient enrolled in a clinical trial and will ensure that they continue to have the opportunity to receive the full benefit of those trials."

In recent months, group chairs and professional societies have challenged NCI with unprecedented resolve.

Group chairs wrote a letter to NCI Director Harold Varmus, stating that the cuts have precipitated a "crisis" in clinical research (The Cancer Letter, April 4).

Varmus has not responded to the letter directly.

However, in a recent call with advocates, NCI officials said that group chairs would be urged to meet with NCI officials separately, and after these separate meetings are concluded, they would meet as a group. Varmus would be present at that meeting, institute officials promised advocates.

In the same conference, NCI officials said that they would be open to fine-tuning the group budgets (The Cancer Letter, May 2).

Recently, the institute has reversed its position on funding of a component of the clinical research program.

When community clinics that accrue patients to NCI studies objected to the institute's plan to leave them operating without funds through the summer, Varmus said the funding gap was never a part of the institute's plans and blamed what he characterized as a misunderstanding, which he said was caused by the institute's failure to communicate clearly (The Cancer Letter, April 11).

The controversy caused several clinics to contact their elected representatives, who, in turn. contacted NCI.

Indeed, NRG's Curran said the cooperative groups have political clout.

Most congressional districts don't have NCI-designated cancer centers.

"The only way NCI money comes to most districts for cancer research is through the network groups," he said. "It's a modest amount in each case, but it's the only federally-funded cancer research in most districts."

The statements from the groups follow:

ECOG-ACRIN

We are concerned over recent changes to the federally funded clinical research program sponsored by the National Cancer Institute.

Our major concern is that adequate resources may not be available to continue providing the best science-based clinical trial opportunities for the many patients we serve. The current ECOG-ACRIN portfolio of trials includes investigations of targeted agents and new approaches to imaging technologies and statistical designs.

We must maintain a strong infrastructure (scientific programs, operations, biostatistics, data management, auditing, etc.) to support such opportunities, which continually flow into the public system from our scientific committees, whose members are expert clinical and laboratory researchers. These capabilities are essential to ensure the integrity of our trials and patient safety. Discussions are ongoing with the NCI, and we are working on solutions; however, it is unclear as to how we can preserve these critical capabilities within the current funding structure.

With the launch of the National Clinical Trials

Network (NCTN) on March 1, 2014, an entirely new algorithm was introduced for funding publicly sponsored clinical trials. Funding for core capabilities is now determined by the number of patients the NCI projects that we will accrue each year.

Rather than having a fixed annual amount for core support over the 5-year grant period (which also began on March 1), core support will now ebb and flow each year as trials open and close and accrual fluctuates accordingly. Although some efforts are clearly linked to accrual and some fluctuation in funding may be in order, the current process does not account for the significant costs to maintain our scientific community and to design, develop, execute, and monitor new trials. What is not covered is the cost of ongoing treatment and follow-up of patients after accrual. The process does not provide a mechanism to proactively adjust support based on trial activity.

A quota system for patient accrual went into effect March 1—quite literally, overnight—with a proposed ceiling of 17,000 accruals per annum overall. About 12,000-13,000 of the slots are available for adult cancer patients, and the remainder are available for children with cancer. For the past 2 years, patient accrual was more than 21,000 patients (averaging 23,674 patients over the past 7 years).

The accrual target of 17,000 patients has imposed an unplanned reduction of about 4000 adult patient accrual opportunities. This decrease is inconsistent with our existing accrual rates in NCI-approved studies. For instance, the accrual target for ECOG-ACRIN was set at 2772 for both therapeutic and advanced imaging studies during the first year of the NCTN, whereas we estimate that accrual to our current studies will reach about 3150. Not only will we consume all of the allocated slots for the existing studies and those approved to open this year, we will also require additional funding. We cannot ethically, morally, or with any scientific responsibility, close current studies, to which patients have consented and institutional review boards have approved.

So, what is at stake? New scientific initiatives. There are a number of new efforts in progress that are not included in the accrual calculation noted above. Among these are 30 studies developed by ECOG-ACRIN scientific committees that are currently in, or being prepared for, NCI review. We have been commissioned to coordinate international trials to evaluate new approaches for rare tumors, such as anal, penile, and thymoma. Some studies employ immune checkpoint inhibitors and various tyrosine kinase inhibitors, and some are aimed at common cancers, such as lung, breast, prostate, and colon, and their molecular subtypes. Our investigators, staff, and patient advocates have worked diligently to move these studies forward.

Will they see the light of day? The ECOG-ACRIN infrastructure is supporting a major new NCTN initiative based on molecular characterization of patients' tumors, accrual to which is scheduled to begin this year. ECOG-ACRIN has been designated by the NCI to provide the various components of the NCTN with highly technical scientific, operational, informatics, and biostatistical expertise to evaluate new imaging agents in advanced imaging trials. The results of these trials will enhance the NCTN's ability to conduct more efficient studies.

Although the grant year began without a Notice of Grant Award, we were provided with preliminary funding estimates on March 1. The estimates indicated cuts totaling over $4 million and were confirmed when we received our Notice of Grant Award on April 29. The cuts have led to the loss of several million dollars in support of our laboratory programs, researchers, and institutions.

More than 20 FTEs were released from our operations and biostatistical centers. Lost were experienced research personnel across therapeutic and diagnostic imaging disciplines that had already been deemed essential following our merger in 2012. We are not alone. Other groups and our member institutions, which we value greatly, are facing similar situations.

The financial and programmatic elements of the accrual-based funding algorithm of the new NCTN were poorly planned and abruptly implemented without adequate transition planning. Although the new NCTN announcements come with promises of a vastly improved system, these actions have far-reaching implications that threaten the continued viability of a publically funded clinical trials program.

—Robert Comis and Mitchell Schnall, group co-chairs

Alliance:

During the Alliance Spring Group Meeting last week, our members reviewed our existing portfolio of clinical trials, and re-affirmed our commitment to this important work. The meeting was scientifically exciting.

The outstanding, highly experienced Alliance research teams use innovative study designs to integrate new therapeutics, including many new molecularly-

targeted agents, into multidisciplinary treatment for a wide variety of cancers. Each of our current studies is the result of many months or years of researcher and patient commitment and addresses important issues that stand to significantly improve patient outcomes.

We have a large network of dedicated physicians who provide access to clinical trials throughout the US, and Alliance members remain committed to doing whatever it takes to achieve the very best possible results for our patients. Our broad community scope allows patients access to new cancer treatments in their own communities, and helps ensure that the practice of cancer medicine is up to date across the country.

Unfortunately, at a time when opportunities for exciting research are more numerous than ever before, we are struggling with issues related to the launch of the NCTN. The former cooperative group system, which evolved over almost 60 years, had arrived at an equilibrium balancing number of studies with patient accrual (29,200 per year at its peak).

The NCTN now has a cap on accrual of 17,000 patients per year, with only 12,000 allocated to adult patients. There was no phase-in period for this accrual reduction, and for the studies currently in the Alliance portfolio, we will exceed our allocated numbers if accrual proceeds as projected.

Do we respond to these pressures by closing current studies so that we can open new ones? Do we put a hold on all new studies? For how long? We also experienced a major reduction in our operations budget, which is linked to number of accruals. This leads to more difficult choices.

Should we prioritize new studies based upon having at least one study for each disease, or according to which studies have the highest potential impact, or give consideration only to studies that are the right size to fit our accrual cap and operations funding? How do we motivate our scientific leaders to continue their volunteer work to develop new trials when it is clear that the system cannot accept the great majority of these studies? How can we continue to ask our member institutions to open trials when accrual capacity fluctuates but their costs of operation remain fixed? These are just a few of the questions raised by our researchers.

Cancer clinical trials are a complex endeavor. They require active partnership between patients, treating physicians, scientists and society at large (to fund the research). Achieving the best scientific results requires the flexibility to align funding and accrual capacity with available research opportunities. In addition, each clinical trial is a commitment – to both patients and researchers – to answer an important question that impacts people's lives. We are concerned that the NCTN, as currently configured and resourced, will not meet these requirements for excellence.

—Monica Bertagnolli, group chair

SWOG:

The following email was sent to SWOG investigators on April 25:

In recent weeks, there has been much said and written in clinical oncology circles regarding NCI funding cuts for the cooperative groups, within the new National Clinical Trials Network. However, most of us didn't receive actual Notices of Award (NOA) from the NCTN until just last week, and I did not wish to post a message about budget issues until we had those official NOAs in-hand and knew precisely what our financial situation was.

It's a mixed picture: SWOG's combined Operations Center and Statistical Center grant awards represent a slight increase in funding over our 2013 levels, but somewhat less than we had budgeted for and requested in 2014. As noted in the pre-award notices from the NCI, the grants take into account "the total funding anticipated for the entire NCTN program, the accrual estimated for the program [as well as our likely proportional share], and the application's impact scores." We can be proud that SWOG plans were well received by reviewers and that ultimately the funding was fairly allocated in respect to percent accrual to SWOG studies. However, the overall budget cuts to the Groups are real and must be taken quite seriously. SWOG itself still has a small budget deficit to make up.

We will look increasingly to non-NCI sources of support, including our own Hope Foundation, but the Foundation is not a panacea. SWOG leadership meets with the NCI to discuss our specific awards in coming weeks; if we can't make up the differences, we will soon after formally assess our priorities and start making what might be tough decisions, while, of course, trying to increase efficiencies. It is likely they will be focused rather than across the board cuts. I can say investigators should keep proposing trial ideas, and that good ideas will still move forward. In a tight fiscal environment, one in which we know potential network accrual may carry caps, working together across Groups will be even more essential, and we look forward to deeper discussions, and more fruitful collaboration with the other Groups.

Finally, we are still waiting to receive word on the status of our application to hold an NCORP Research Base, which also represents a significant proportion of

Operations/Statistical Center activity. SWOG has a wealth of scientific expertise relative to NCORP goals, and we hope our application will be well received. Much of our planning for the next few years rides on that, especially our plans for expanding cancer care delivery research.

Financial challenges in conducting cancer research are commonplace, and we will certainly weather this test. Despite recent gloominess and even concern, the Groups continue to strive to conduct essential clinical research serving the public interest in general, and cancer patients more specifically. SWOG will carefully consider our financial priorities, fund the most promising and innovative projects, and do everything we can to ensure that important studies, like the Lung Master Protocol discussed previously in this space, are implemented and completed. Our patients expect and merit no less.

SWOG lives to fight cancer another day!

—Charles Blanke, group chair

Advocate's Perspective:

These are interesting data, but like most attempts to get a full picture, falls way short, which is why this whole situation is reprehensible.

There ought to be a comprehensive view of the KPIs (key performance indicators) of this very critical, very large, very complex system. We are investing over $150MM in clinical research to improve the standard of care, to reduce the human suffering attributable to cancer.

Yet, those charged with running the system, and those who depend on the system delivering results are kept in the dark, with the NCI hiding behind technicalities about confidentiality where it is clearly possible to provide a better overview without breaking any of the rules. One need only look to the public databases that NIH keeps of all of its grant awards.

We can find individual components of the $150 million by searching, but there is no tagging or categorization that would allow us to pull out all of the grants that comprise the $150 million. Why is it that we cannot have access to a list of the component grants? Why is it that the NCI cannot share its own list of grants that tie back to the $150 million. Clearly, this list must have been drawn up before the awards were made final.

Instead, we are working with snippets that tell a part of the story, which doesn't give us enough information to provide constructive input. NCI will meet individually with the group chairs and perhaps also meet with them as a group. But, no one outside of NCI has ready access to the full picture.

This is different than what has occurred in the past. Below is an exhibit provided by NCI some years ago when the 2011 budget was published. We do not understand why that have chosen not to provide this macro-level view in this round of budget cuts.

With the degree of carnage to the operating and stat budgets, as well as the accrual capitations, it is so much more important to have this information if the system's administrators and stakeholders and funders are to work together to find a way through these

Base Divisional Set-Aside for Network/ Group Program *	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011 (Estimated)	Grand Total (Over 6 Yrs)	% Grand Total
Group Operations & Statistical Centers (including Capitation for Majority of Accrual)	$128,833,204	$126,516,480	$126,141,046	$126,380,185	$127,127,666	$120,304,563	$755,303,144	78.7%
Participating Site U10s	$ 12,532,773	$11,375,647	$11,074,808	$11,241,179	$11,823,333	$10,839,407	$ 68,887,147	7.2%
Core Services for Imaging & RT (RPC, QARC)	$ 4,185,608	$4,302,227	$ 4,271,987	$ 4,224,437	$ 4,307,091	$ 4,131,527	$25,422,877	2.6%
Subtotal	$145,551,585	$142,194,354	$141,487,841	$141,845,801	$143,258,090	$135,275,496 **	$849,613,167	
Estimated CTSU Capitation	$ 4,000,000	$ 3,779,781	$ 4,289,927	$ 5,162,362	$ 5,174,165	$ 5,040,000	$ 27,446,235	2.9%
Subtotal	$ 149,551,585	$145,974,135	$145,777,768	$147,008,163	$148,432,255	$140,315,496	$877,059,402	
ACRIN	$7,002,444	$15,442,054	$13,129,762	$13,509,478	$12,816,778	$10,612,813	$ 72,513,329	7.6%
ATC	$1,644,551	$ 1,749,999	$ 1,716,026	$ 1,716,026	$1,716,030	$ 1,716,026	$ 10,258,658	1.1%
Grand Total	$158,198,580	$163,166,188	$160,623,556	$162,233,667	$162,965,063	$152,644,335	$959,831,389	100.0%

* Does not include ARRA funding and special "one-time" supplements (e.g., transition supplements) or funding provided by other NCI/NIH Programs for Special Initiatives (e.g., complexity funding)

** Base funding was decreased by FY2011 general budget cuts

treacherous times.

At our ECOG-ACRIN group meeting this past week, there were many discussions about this situation, some with NCI representatives in the room. It is disheartening to hear the interactions between the groups and NCI, as there is far too much finger-pointing, with one blaming the other for the current state of affairs.

As advocates, as representatives of the ultimate consumers who depend on this system, who is at fault is irrelevant. It is clear that we are in a situation now where things have been set in motion that will harm the system and impact both the science and patient outcomes.

It's too late to prevent that. It's our job now to all pull together and understand the implications of what's been done and work through our collective actions to minimize the damage.

At our Cancer Research Advocates Committee meeting, we presented a historical perspective on this initiative. One can go back to the public comment that we prepared in response to the IOM report and our comments at the IOM Implementation workshop and see that the concerns that we raised and the suggestions we made for addressing them were all too valid.

NCI has not brought what would be considered Transformation 101 principles to this effort to transform the NCI-funded clinical trials enterprise. One needs to have a clear baseline and targets, as well as a plan that identifies how one gets from baseline to target, with metrics to monitor the transition.

This is not the case with this transformation. So, it is no surprise that things are coming off the rails at this point. Rather than admiring the problem, we need to focus on where we stand and get our collective act together on a go-forward basis.

One of our committee members raised the question of what we should do at this point, what were the next steps? At this point, we need to hunker down and get organized for a long, difficult effort to get things back on track.

This is similar to what occurred after the last effort to transform the system, which took place over a decade ago and involved a number of initiatives, some more successful than others, including the Clinical Trials Support Unit (CTSU), the Central IRB, State of the Science meetings, Concept Evaluation Panels. It is unfortunate that we seem not to learn from prior efforts and put ourselves in the position of damage control as opposed to doing it right the first time.

When the IOM report was published, our comment letter, signed by over 70 of the cooperative group advocates compared the transformation plan to a "single armed trial with an ambiguous schema, with no dose modification plan, unclear primary endpoints and weak data monitoring."

I think that our comparison was all too valid. It

is very frustrating that scientists who understand the principles that go into a well-controlled experiment somehow don't see the value of these basic principles when they are undertaking transformation of an enterprise of this scale.

Doing the right thing would mean shifting some funding internally witin NCI or getting additional funding for NCI to minimize the damage. But, at this point, that isn't likely to happen.

Our challenge now is to get beyond the finger-pointing and the excuses to figure out how we can all best work together to get the best result for our constituents, for whom this is a matter of life and death.

—Michael Katz, patient advocate

AAUP Demands Reinstatement Of MD Anderson Faculty Members

(Continued from page 1)

The investigation was requested by Douglas Boyd, a professor in the MD Anderson Department of Cancer Biology and chair of the PTC Issues Committee. In an email to AAUP, Boyd outlined his case for the investigation with meeting minutes and presentations.

The AAUP letter, dated May 13, begins with description of the cases of the two affected faculty members—Kapil Mehta and Zhengxin Wang—whose tenure renewal applications were vetoed by DePinho.

"Our Association's interest in the cases of Professor Mehta and Professor Wang stems from its commitment to basic tenets of academic freedom, tenure, and due process, as enunciated in the 1940 Statement of Principles on Academic Freedom and Tenure, jointly formulated by the AAUP and Association of American Colleges and Universities (AAC&U) and endorsed by several hundred educational and scholarly organizations," said the letter from Gregory Scholtz, AAUP associate secretary and director of the Department of Academic Freedom, Tenure, and Governance.

MD Anderson may join over 50 institutions on AAUP's censured list if a formal investigation is initiated and if DePinho's administration is found to have run afoul of AAUP governance standards.

Founded in 1915, AAUP represents 47,000 faculty members, with more than 300 chapters and 33 state organizations throughout the U.S.

"Assuming the essential accuracy of what Professor Mehta and Professor Wang have reported to us, we are deeply troubled by the quantity and severity of the departures in their cases from the aforementioned principles and academic standards," the letter reads.

"The information in our possession regarding the cases of Professor Mehta and Professor Wang has come primarily from them, and we appreciate that you may have additional information that would contribute to our understanding of what has occurred.

"We have emphasized the seriousness of our concerns over how these cases have been handled, and we await your prompt response.

"Assuming the essential accuracy of the foregoing account, we would strongly urge you to rescind the notice of non-reappointment issued to both professors and immediately reinstate them to their full-time appointments. Our further course of action in these cases will depend upon how you will act now."

Boyd filed a request for an AAUP investigation April 28:

"It is clear that our institution is not adhering to practices espoused in either the '1940 Statement of Principles on Academic Freedom' or the '1958 Statement on Procedural Standards in Faculty Dismissals,'" Boyd wrote in an email to AAUP First Vice President Hank Reichman and President Rudy Fichtenbaum.

"Pursuant to the discussions with you and Dr. Fichtenbaum as to the denial of tenure renewal (University of Texas MD Anderson Cancer Center) for several of our faculty who received UNANIMOUS votes by our Promotions, Tenure Committee, as an AAUP member, I hereby request a formal investigation by Committee A on this matter," Boyd wrote April 28.

"As you know a faculty senate committee charged with investigating this denial of tenure renewal reported that the four faculty members involved were indeed qualified for renewal and made several recommendations to the Administration all of which were ignored."

It is unclear whether a formal investigation will be conducted, said Reichman, chair of AAUP's Committee A on Academic Freedom & Tenure.

"Prof. Boyd's request was referred to our staff," Reichman said to The Cancer Letter. "A decision to initiate a formal investigation is made by the Executive Director, but usually only after other [mediation] efforts by our national staff have failed."

The UT System declined to comment.

"A letter was received by Dr. DePinho within the last three business days from the American Association of University Professors. The correspondence included some misunderstandings of both the tenure system at The University of Texas MD Anderson Cancer Center and the particular circumstances of the individuals

discussed in the letter." said MD Anderson spokesman Jim Newman.

"The tenure system at The University of Texas MD Anderson Cancer Center has successfully withstood the tests of both time and court challenge, and provides both appropriate due process and protection of academic freedom to those who have chosen to pursue and maintain employment as tenured faculty at our institution.

"Because we take the accusations made in the letter seriously, we are somewhat surprised that we would be asked to respond to those accusations on such short notice before making a detailed response to the sender, which will be sent at the appropriate time and in an appropriate manner."

AAUP: "Term Tenure" is "Oxymoronic"

MD Anderson's "term tenure" system is not tenure, AAUP said.

"Of primary concern is that what UTMDACC Institutional Policy #ACA0024 refers to as 'term tenure' has nothing to do with continuous or indefinite tenure, as understood in American higher education," the letter reads.

"A tenured appointment is, by definition, not a term appointment. These 'term tenure' appointments are seven-year term appointments, pure and simple.

"'Term tenure' is not only oxymoronic but misleading.

"We note that Rule 31007 of the UT System Rules and Regulations of the Board of Regents uses the designation 'seven-year term appointment,' not 'term tenure,' to specify the academic appointments available at the center, thus confirming the lamentable fact that there is no tenure—and thus no meaningful safeguards for academic freedom—at the MD Anderson Cancer Center."

The AAUP Letter

The text of AAUP's letter to DePinho follows:

Dear President DePinho:

Dr. Kapil Mehta, professor of biochemistry in the Department of Experimental Therapeutics, and Dr. Zhengxin Wang, associate professor in the Department of Cancer Biology, with thirty-two and thirteen years, respectively, of full-time service at the MD Anderson Cancer Center, have sought the advice and assistance of the American Association of University Professors as a result of having been notified of the nonrenewal of their "tenured" appointments.

Professor Mehta, who accepted his initial appointment at the cancer center in 1983, has provided us with the following account of his case.

In August 2011, he learned that his department had recommended that his seven-year term appointment (so called "term tenure") be renewed for the fourth time. In November, the then-senior vice president for academic affairs, Dr. Oliver Bogler, notified him that the institution's Promotion and Tenure Committee (PTC) had unanimously approved his reappointment.

In May 2012, Dr. Bogler informed him that you had declined to accept the recommendations of the department and the PTC, a decision confirmed in an August 1 "memorandum of appointment" from you notifying him that his request for renewal of appointment had been "DISAPPROVED," with his appointment expiring in August 2013.

No reason was given for the decision, and Professor Mehta's subsequent requests for a written explanation of the basis for the decision have been unavailing.

Encouraged by the then-provost and executive vice president, Dr. Ray DuBois, Professor Mehta that summer filed an appeal with the Faculty Appeal Panel (FAP) citing the provisions of the Faculty Appeal Policy (UTMDACC Institutional Policy #ACA0041), even though the policy requires all such appeals to be submitted to the president.

In October 2012, the interim provost and executive vice president, Dr. Thomas A. Buchholz, notified Professor Mehta that, after reviewing the recommendations of the PTC and the FAP, he had decided to sustain your decision not to renew Professor Mehta's appointment.

With the intervention of the faculty senate, Professor Mehta obtained a copy of the FAP's report, which, he discovered, had sustained his appeal and recommended a "1-2 year grace period."

Following a December 2012 meeting with you, in which Professor Mehta was accompanied by another senior faculty member, he received your December 31 memorandum notifying him of your "final decision" not to rescind his nonreappointment.

In June 2013, his department and division chairs joined in making an additional request to the new provost and executive vice president, Dr. Ethan Dmitrovsky. They asked for a two-year extension of his appointment inorder to allow him to complete a "promising" cancer-research project. That request was declined.

Professor Wang, whose career at MD Anderson

began in 2001, has informed us of the following events.

In an April 30, 2013, memorandum, the PTC notified Professor Wang of its unanimous finding that he was "qualified for a renewal of term tenure" and of its having "forwarded a favorable recommendation" to the administration.

Then, by letter of May 28, 2013, the interim provost and executive vice president, Dr. Buchholz, notified Professor Wang that his appointment would not be renewed, with his current appointment ending August 31, 2014.

The letter provided the following explanation: "The reasons for nonrenewal are that your renewal of term tenure was not approved." The letter also informed Professor Wang that if he wished for a review of the decision, he should send his request to Dr. Buchholz.

On May 31, 2013, Professor Wang wrote to ask Provost Buchholz for a meaningful statement of the reasons for the nonreappointment. He has not received a response. On June 18, he filed his appeal with the interim provost.

In August, while the appeal was still pending, he received from you a "memorandum of appointment" dated August 1 notifying him that his application for renewal of "tenure" had been "DISAPPROVED" and that the 2013-14 academic year would be his last at MD Anderson.

On August 15, the new provost, Dr. Dmitrovsky, informed him that his appeal was denied.

Our Association's interest in the cases of Professor Mehta and Professor Wang stems from its commitment to basic tenets of academic freedom, tenure, and due process, as enunciated in the 1940 Statement of Principles on Academic Freedom and Tenure, jointly formulated by the AAUP and Association of American Colleges and Universities (AAC&U) and endorsed by several hundred educational and scholarly organizations.

Derivative procedural standards are set forth in the 1958 Statement on Procedural Standards in Faculty Dismissal Proceedings, also jointly formulated by the AAUP and the AAC&U, and in the AAUP's Recommended Institutional Regulations on Academic Freedom and Tenure.

As you are probably aware, the 1940 Statement asserts the necessity of academic freedom "for the common good," as advanced by "the free search for truth and its free exposition." The academic freedom of faculty members is protected by a system of "permanent or continuous tenure," in which, "after the expiration of a probationary period, teachers and investigators" will have their "service ... terminated only for adequate cause, except in the case of retirement for age, or under extraordinary circumstances because of financial exigencies."

The complementary 1958 Statement sets forth standards for "acceptable academic practice" regarding dismissal of a tenured faculty member. These procedural standards (further elaborated in Regulations 5 and 6 of the Recommended Institutional Regulations) require, among other elements, an adjudicative hearing of record before a duly constituted faculty body in which the administration demonstrates adequate cause for dismissal.

The academic freedom of full-time faculty members who have not yet completed their probationary period, which the 1940 Statement confines to seven years, is safeguarded through the procedural standards incorporated in Regulations 2 and 10 of the Recommended Institutional Regulations.

Key standards are timely notice of nonreappointment (Regulation 2c), a written statement of the reasons for the decision (Regulations 2e-f), and the opportunity to contest a nonrenewal with a duly constituted faculty body (Regulations 2g and I 0).

Assuming the essential accuracy of what Professor Mehta and Professor Wang have reported to us, we are deeply troubled by the quantity and severity of the departures in their cases from the aforementioned principles and academic standards.

Of primary concern is that what UTMDACC Institutional Policy #ACA0024 refers to as "term tenure" has nothing to do with continuous or indefinite tenure, as understood in American higher education. A tenured appointment is, by definition, not a term appointment.

These "term tenure" appointments are seven-year term appointments, pure and simple.

"Term tenure" is not only oxymoronic but misleading.

We note that Rule 31007 of the UT System Rules and Regulations of the Board of Regents uses the designation "seven-year term appointment," not "term tenure," to specify the academic appointments available at the center, thus confirming the lamentable fact that there is no tenure—and thus no meaningful safeguards for academic freedom at the MD Anderson Cancer Center.

The AAUP regards all full-time faculty members, regardless of their institution's regulations, as serving either on probationary appointments or on appointments with continuous tenure (Regulation 1b

of the Recommended Institutional Regulations).

The Association accordingly expects institutions to afford full-time faculty members whose length of service has exceeded the maximum period of probation the due-process protections of tenure, as set forth in the 1958 Statement and elsewhere, and to afford full-time faculty members whose length of service is seven years or less the due-process protections set forth in Regulations 2 and 10 of the Recommended Institutional Regulations.

Clearly, Professors Mehta and Wang have served well beyond what the academic community at large would consider a reasonable period of apprenticeship.

As a result, under normative academic standards, their appointments are terminable only for cause as demonstrated in a proceeding such as that outlined in the 1958 Statement.

Even had their length of service been confined to a single renewable term, they would have been entitled to a written statement of reasons upon nonreappointment, which neither of them received, and to the opportunity for faculty review, which, inexplicably, Professor Mehta received and Professor Wang did not.

With respect to reasons, under widely accepted principles of academic governance, as articulated in the enclosed Statement on Government of Colleges and Universities (jointly formulated by the AAUP, the American Council on Education, and the Association of Governing Boards of Universities and Colleges), an administration should accept the recommendation of a faculty body, such as the PTC and the FAP, "except in rare instances and for compelling reasons which should be stated in detail."

We are not aware that these two bodies were furnished compelling reasons stated in detail.

The information in our possession regarding the cases of Professor Mehta and Professor Wang has come primarily from them, and we appreciate that you may have additional information that would contribute to our understanding of what has occurred.

We have emphasized the seriousness of our concerns over how these cases have been handled, and we await your prompt response.

Assuming the essential accuracy of the foregoing account, we would strongly urge you to rescind the notice of nonreappointment issued both professors and immediately reinstate them to their full-time appointments.

Our further course of action in these cases will depend upon how you will act now.

Sincerely,

Gregory Scholtz

Associate Secretary and Director

Department of Academic Freedom, Tenure, and Governance

Report: Rising Treatment Costs Due to 340B Discounts

The 340B drug discount program is causing a rise in the costs of treating cancer patients, according to a new report.

Published by the IMS Institute for Healthcare Informatics, the report, "Innovations in Cancer Care and Implications for Health Systems," showed that marketplace behaviors, triggered by a lack of eligibility integrity, are a major reason for increasing costs of cancer care, said the Alliance for Integrity and Reform of 340B in a statement.

According to the analysis, growing numbers of hospitals are acquiring independent, private oncology practices in order to maximize the amount of revenues they can receive from the drug discount program that was intended to help needy patients, the alliance said.

"Accountable Care organizations and health and health care organizations that are covered by the 340B Drug Discount Program have expanded their presence in oncology, moving more patient care from physician offices to hospital outpatient facilities," the report said. "To reflect hospitals' higher costs and overheads, they receive higher reimbursement to administer drugs compared to physician offices.

"For typical therapies that are infused or injected by an oncologist, reimbursed costs for hospitals are at least double those for physician offices, sharply increasing costs to payers over the past two years.

"Patient out-of-pocket costs are then driven higher, depending on the patient's insurance plan and benefit design, which can trigger reduced levels of therapeutic persistence by the patient and higher overall cost of care."

The IMS report confirms what numerous studies have—that costs increase for patients and insurers with cancer care shifting to hospitals, said Ted Okon, executive director of the Community Oncology Alliance.

"Cancer is a disease that exacts an emotional and financial toll on people, yet public policy is creating

access problems and driving up costs by incentivizing care away from the most accessible, cost-effective setting," Okon said in a statement.

The 340B program has been growing in utilization since its inception in 1992, when it was created by Congress to support access to prescription drugs for vulnerable, uninsured and indigent populations, according to the alliance.

"Congress envisioned that 340B would be used by true safety net hospitals, but the eagerness of many hospitals to capture additional revenues, without necessarily passing on benefits to indigent, uninsured patients, has led to more than 2,000 hospitals taking part in 340B today," said alliance spokesperson Stephanie Silverman.

According to the IMS study, the Affordable Care Act has had the unintended consequence of further expanding the 340B program by making more hospitals eligible to participate in the program.

"While the proportion of uncompensated care has remained steady over the past several years—essentially a proxy for the proportion patients that enable a hospital to qualify for these discounts—the percentage of total hospital drug purchases using these discounts is up nearly 20 percent from six years ago," the report said.

"Hospitals can use 340B purchasing discounts for oncology practices that they have acquired while still charging facility-level prices to commercial payers.

"The ACA has also facilitated the formation of ACOs, further encouraging hospitals to purchase oncology practices to infuse cancer drugs in the hospital outpatient setting.

"Separately, low reimbursement for cancer treatments administered in the oncologist's office, by both government and commercial payers, leads the oncologist to 'refer' the patient to the hospital for drug administration."

TGen and George Mason Form Precision Medicine Alliance

The Translational Genomics Research Institute and George Mason University announced a strategic research alliance May 6.

Called the TGen-George Mason Molecular Medicine Alliance, the effort is designed to recommend medications and treatments to clinicians based on each patient's molecular profile.

The alliance has submitted applications for more than $12 million in research grants for projects each organization might not have pursued on its own, the statement said.

"By combining efforts, George Mason and TGen look to develop a more precise research strategy to help people afflicted by cancer and other diseases, while pursuing additional research," the statement said.

A non-profit genomics research institute located in Phoenix, Ariz., TGen was established by Jeffrey Trent, the founding scientific director of the National Human Genome Research Institute.

"The Molecular Medicine Alliance is an opportunity for two highly regarded institutions to integrate their complementary knowledge and human resources to help patients by using state-of-the-art technology to advance new therapeutics options," said Jeffrey Trent, TGen president and research director.

By integrating genomics and proteomics, the alliance said it will initially focus on new treatments for metastatic breast cancer or melanoma. Research will also focus on the development of vaccines for infectious diseases, and biomarkers that can help diagnose traumatic injuries such as brain concussions.

"This is a major achievement for science and health care," said GMU President Ángel Cabrera. "By joining forces, researchers can understand disease at a more refined level and more people can be helped. This is the level of research that all universities and companies strive to achieve."

GMU is home to the Center for Applied Proteomics and Molecular Medicine, which is run by co-directors Lance Liotta and Emanuel Petricoin, former employees at NCI and FDA, respectively.

Liotta and Petricoin joined GMU in 2005 after NIH implemented more stringent conflict-of-interest regulations that would ban all agency employees from accepting consulting fees, stock options, or any compensation from the industry.

In 2004, Liotta and Petricoin were brought before a House subcommittee that investigated conflicts of

interest at NIH (The Cancer Letter, May 21, 2004).

Then a laboratory chief at NCI, Liotta, while leading the federal government's collaboration with a Maryland company to develop OvaCheck, a test for early detection of ovarian cancer, accepted $70,000 in consulting fees from a competing firm, Biospect Inc., from late 2002 to mid-2004.

Liotta's research partner, Petricoin, then an FDA employee based at NIH, also accepted fees from Biospect with the permission of his superiors.

In a March 7, 2005, email to his NCI colleagues regarding joining GMU, Liotta wrote:

"It was a very hard decision to make, but I couldn't pass up the exciting opportunity offered by GMU. The newly created GMU center will synergize with the world-class GMU expertise in mathematics, engineering, life sciences and nanotechnology, combined with the access to renowned clinical expertise provided by the GMU partnership with [Inova]. The mission of the center will be to accelerate the transition of basic science discoveries in the world of proteomics to innovative clinical research and patient-tailored medicine." (The Cancer Letter, March 11, 2005)

In Brief

Oncology Nursing Society Names Board of Directors

THE ONCOLOGY NURSING SOCIETY announced its 2014-2015 board of directors at its 39th Annual Congress.

Margaret Barton-Burke was named president for a two-year term. She is the Mary Ann Lee professor of oncology nursing at the University of Missouri and a research scientist at Siteman Cancer Institute.

Tracy Gosselin, will continue her role as treasurer. Gosselin is associate chief nursing officer and assistant vice president at the Duke Cancer Institute. **Marlon Garzo Saria** continues in his role as secretary. He is an advanced practice nurse researcher at the University of California, San Diego.

The society's newly elected directors-at-large are **Donald "Chip" Bailey Jr.**, associate professor at the Duke University School of Nursing, and **Colleen O'Leary**, a clinical nurse specialist at the Ohio State University Comprehensive Cancer Center Arthur G. James Cancer Hospital and Richard J. Solove Research Institute.

Directors-at-large continuing their terms are: **Deborah Kirk Walker**, assistant professor and nurse practitioner at the University of Alabama at Birmingham School of Nursing; **Anne Ireland**, clinical director of the solid tumor malignancy program at City of Hope National Medical Center; and **Susie Newton**, senior director of health management solutions at Quintiles.

Director-at-large **Barbara Biedrzycki**, a nurse practitioner at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, stepped down from the board in March. The board of directors voted to have director-at-large **Vicki Norton**, whose term would have expired this year, extend her term for one additional year to fill the unexpired portion of Biedrzycki's term. Norton is the clinical nursing director at Park Nicollet Methodist Hospital.

THE AMERICAN COLLEGE OF RADIOLOGY named new officers during its 91st Annual Meeting and Chapter Leadership Conference.

Bibb Allen, Jr. became the new chair of the board of chancellors. Allen, a diagnostic radiologist in the Birmingham Radiological Group, is former vice-chair of the college's board of chancellors, former chair of the commission on economics and former representative to the AMA/Specialty Society RVS Update Committee. Allen is also chair of the Neiman Health Policy Institute's advisory board.

James Brink was named vice chair of the board of chancellors. Brink is radiologist-in-chief at Massachusetts General Hospital, and the Juan M. Taveras Professor of Radiology at Harvard Medical School. He is immediate past chair of the ACR commission on body imaging, co-chair of Image Wisely and serves on the JACR editorial board.

Paul Ellenbogen was elected president by the ACR council. Ellenbogen is a partner in Radiology Associates of North Texas. He served as chair of the board of chancellors from 2012 to 2014, vice chair from 2010-2012, secretary-treasurer from 2006-2010 and held various other leadership roles. Ellenbogen is past president of the Texas Radiological Society and past chair of the department of radiology at Presbyterian Hospital of Dallas. He was awarded the Gold Medal of the Texas Radiological Society in 2009 and the Presidential Award of the American Association for Women Radiologists in 2013. He is a fellow of the ACR in addition to holding fellowship in the American Institute of Ultrasound in Medicine and the Society of Radiologists in Ultrasound.

Deborah Levine was elected vice president by the council. Levine is a leader in academic medicine, serving as vice chair of academic affairs in the

department of radiology at Beth Israel Deaconess Medical Center and chair of the Harvard Medical School longer service committee for promotions. She is a professor of radiology at Harvard Medical School, is the past chair of the ACR Commission on Ultrasound, senior deputy editor of Radiology, and vice president of the Massachusetts Radiological Society.

BRISTOL-MYERS SQUIBB and **Celldex Therapeutics Inc**. entered into a clinical trial collaboration to evaluate the safety, tolerability and preliminary efficacy of nivolumab, BMS's investigational PD-1 immune checkpoint inhibitor, and varlilumab, Celldex's CD27 targeting investigational antibody in a phase I/II study.

Multiple tumor types will be explored in the study, which could potentially include non-small cell lung cancer, metastatic melanoma, ovarian, colorectal and squamous cell head and neck cancers. Preclinical data suggest the combination of these two mechanisms may enhance anti-tumor immune response compared to either agent alone.

BMS will make a one-time payment of $5 million to Celldex and the parties will share development costs. Celldex will be responsible for conducting the study, which is expected to begin in the fourth quarter of this year.

Additionally, the parties have restructured an existing agreement between Celldex and Medarex related to Celldex's CD27 program, and waived certain future milestone payments and reduced future royalty rates that would have been due from Celldex to Medarex. Medarex was acquired by Bristol-Myers Squibb in September of 2009.

MOFFITT CANCER CENTER began a collaboration with **Vermillion Inc**. to produce clinical and economic data to support a new value-based practice model that may improve survival, quality of life and cost-effectiveness of care for patients with ovarian cancer.

The study will be led by Johnathan Lancaster, a gynecologic oncologist and president of the Moffitt Medical Group, and funded through an unrestricted grant from Vermillion.

The first phase will be retrospective, and will benchmark the care standards and variances provided to patients with ovarian, fallopian tube and/or primary peritoneal cancer. The second phase will model improvements in care quality and cost that may be afforded by creating a standardized triage algorithm employing different FDA-cleared or prototype multi-marker blood tests, along with established clinical diagnostic or prognostic factors such as pelvic exams and ultrasound imaging.

The study will measure the baseline triage effectiveness, treatment standards, early outcomes and cost of care for patients diagnosed with an adnexal malignancy. From this baseline, potential improvement in care and cost effectiveness will be calculated for different triage protocols, including molecular or proteomic biomarkers.

THE CHILDREN'S ONCOLOGY DRUG ALLIANCE is joining the research and resources of the **University of New South Wales** and its commercialization arm, **NewSouth Innovations**; **The Kids' Cancer Project**, an Australia-based childhood cancer research charity; **Novogen**, an Australian oncology drug development company; and **Nationwide Children's Hospital** in Columbus, Ohio, to help accelerate development of a therapeutic approach to neuroblastoma.

CODA plans to work with U.S. and Australian regulators to advance clinical trials of an anti-cancer approach that belongs to a class of therapies known as anti-tropomyosins, which target the structure of the cancer cell.

Novogen currently is finalizing pre-clinical research of its two lead dug candidates, with the goal of starting clinical studies in Australian and U.S. patients in 2015. The aim is that the childhood trials in neuroblastoma will be progressed in parallel with trials of anti-tropomyosins and super-benzopyrans for a number of adult cancers.

The Kids' Cancer Project has supported the anti-tropomyosin research program since its beginnings in 1998, providing funding of $9 million to date. The charity also aims to raise a further $2.7 million to support clinical trials of the new medicine in children with neuroblastoma who have exhausted other treatment options.