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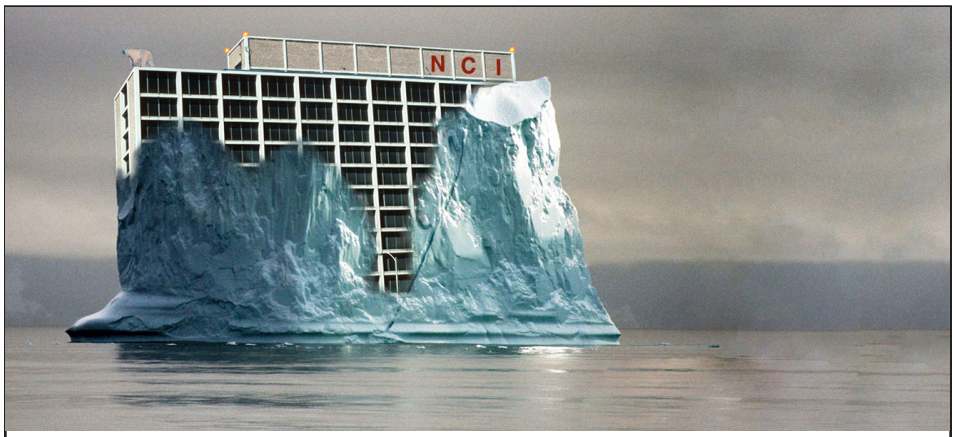

Officials Open to Fine-tuning Group Budgets As Advocates Chip Away at NCTN's Façade

By Paul Goldberg

NCI officials said they plan to hold a series of meetings with clinical trials group chairs and group financial officers in order to fine-tune the new National Clinical Trials Network.

"We are in the midst of one-on-one meetings with the group chairs and their financial people and their statistical leadership, [meeting] group-by-group [to] look at the numbers as they exist, and try to understand from both sides what that research budget will support and what it won't support," said James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis.

(Continued to page 2)

On Biomedical Malthusianism

Varmus, et al. Propose a Strategy For Saving Biomedical Research

By Paul Goldberg

The assumption that growth in research funding would be sustained indefinitely has created an "unsustainable hypercompetitive system" heading toward "long-term decline," a group of scientists, including NCI Director Harold Varmus, wrote in a paper published in the April 22 edition of the Proceedings of the National Academy of Sciences.

(Continued to page 11)

In Brief

CFO Dwain Morris Leaves MD Anderson

DWAIN MORRIS is leaving his job as vice president and chief financial officer of **MD Anderson Cancer Center** to become the chief financial officer for DiabetesAmerica, a multisite provider of comprehensive diabetes care.

(Continued to page 14)

Listen to a Recording Of the NCI Conference Call On Our Website

Advocates Ask NCI to Reveal More Details on NCTN Funding

(Continued from page 1)

"Without seeing, from the group perspective, what the resources can and can't support, it's hard to know from a system-wide perspective how we will move forward."

In a telephone conference the institute convened to respond to concern from advocates, Doroshow said, in effect, that the budgets sent to the groups recently didn't represent fait accompli, and that flexibility was an option.

The May 1 call was organized in response to detailed questions submitted to the institute by an ad hoc group of patient advocates who have been involved in clinical trials, mostly as advisors to NCI and the clinical trials groups.

These advocates aren't members of groups that have large constituencies focused on Washington and Bethesda. Rather they are people who review clinical trials protocols and provide practical advice about the manner in which specific trials and proposed policies would affect clinical trials.

"We have a really big stake in this," said Michael Katz, the advocate who brought the ad hoc group together. "The system is here for us, and we don't want to hear excuses. It doesn't matter who is at fault. You can't clean it up afterwards. If you break it, you can't put humpty-dumpty together again."

The cooperative groups had national structures for coordinating patient involvement, but after the NCI-mandated reorganization, these structures have become nebulous. Lacking organization, Katz reached out to other advocates on ACOR, a listserv.

This way he identified a core group of six veteran advocates and a total of 60 people who wanted to get involved. Ultimately, these advocates put together 17 questions for NCI, and many of them were on the call May 1. There, advocates gave NCI officials the forum to explain their plans for the clinical research network.

NCI officials were informed that a reporter would be on the call, and participants were told that the call would be recorded.

During the call, Doroshow elaborated on the procedure for addressing the concerns of the NCTN groups.

"In addition to the individual meetings that we will be having with the group chairs and their financial officers, we will also have a meeting, which [NCI Director Harold] Varmus will attend, of all of their chairs and their financial individuals, together, to talk through some of these issues," Doroshow said.

"We'd like to have those conversations before any of this becomes widely disseminated, because there are a lot of facts and figures that everyone has to agree to. We need to know the impact of all of these various things. I think it will be different from group to group. It will not be a singular response. It will probably require multiple different responses to try to enhance what the overall network can ensure, what the network can do based on the various circumstances that each of the groups is in."

Written by insiders who understand the clinical research system at least as well as an average investigator, the questions submitted by the ad hoc group of advocates couldn't be answered in an hour-long call.

"We submitted the questions in the spirit of openness," Katz said to The Cancer Letter. "We view the call as the start of the dialogue. The questions are so complex that I think they need to be answered in writing. It's facts and figures; it's concrete stuff. We would like to follow up with NCI to get these questions answered fully, in writing."

NCI hasn't convened any meetings of its principal advisory committees since NCTN was activated on March 1.

In a recent letter to Varmus, the chairs of the adult clinical trials groups that make up the NCTN said in a letter that budget cuts he instituted have triggered a "crisis" in clinical research. In their April 1 letter to Varmus, the chairs of four newly-formed clinical trials groups said that the trials currently conducted by the groups will consume all available resources. "We have determined that the execution of our current active trial portfolio alone will consume the proposed funding, and

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we will have to make decisions that substantially and adversely affect our cancer patients, possibly including, but not limited to closing dedicated disease committees, slowing patient accrual to or closing ongoing studies, and not opening new trials," the group chairs wrote. (The Cancer Letter, April 4).

Varmus hasn't responded to the letter personally, group chairs say.

Similarly, an apparent effort by NCI to interrupt funding for community oncology clinics caused an outcry and a flurry of congressional interest. Varmus responded to that controversy with "an open letter to the cancer community," assuring researchers that funding for the NCI Community Clinical Oncology Program sites would continue as it morphs into the NCI Community Oncology Research Program. "While this was always our intention, this has not been clearly communicated," Varmus wrote.

Official correspondence and interviews indicate that the NCI plan, as originally described, was to force these clinics to find the resources to fill the funding gap between June 1—the day CCOP ends—and sometime in September, when NCORP begins (The Cancer Letter, April 11).

An audio recording of the conference is posted on The Cancer Letter website. *A transcript of the question-and-answer session follows:*

AMY BULMAN [acting director of the NCI Office of Advocacy Relations]: We received a lot of questions in advance for today's teleconference.

One that we received in multiple ways was around "Can NCI share peered-reviewed scores of those parties that participate in NCTN and how is funding related to the review the components of NCTN?" So with that I think I will turn it over to Dr. Doroshow and Dr. Abrams.

JEFFREY ABRAMS [NCI acting director for clinical research]: As far as funding goes, it's a pretty obvious question, and I understand that everyone would like to know that, but we at NCI treat that information in terms of what the actual application is submitted by the grantee.

We treat that as confidential, I'm sure you can appreciate that. It isn't the NCI's role to give out that information. Obviously grantees can give it out, they are free to do that. But we have to treat it as confidential because it is a scientific competition to get these awards.

Similarly, we don't give out peer review scores. We treat that as confidential because that is part of our agreement with the investigators who submit their applications.

BULMAN: Kind of along those lines, can NCI share the requested and official budgets for NCTN?

ABRAMS: Similarly for the actual awards to grantees, the budget for the NCTN—the entire program, all of its components—is $151 million dollars this fiscal year, the year 2014, which was stable compared to last year's budget.

We don't, again give out the individual awards, because, as I said, these come through a competition, the pricing is competitive, and for that reason we respect the grantees' confidentiality here. The grantees are free to give it out, if they wish.

RICHARD BANGS [advocate]: I'd like to use question #14 that was pre-submitted: "What changes in process or outcomes had not been achieved to date, versus the original NCTN vision, what key performance indicators being used to monitor progress are, and what results to date are?"

I don't expect you to give me a detailed answer for this. That would be impossible in this call. I would like to get a general flavor, but I would also like to understand when we would get a written response to that question in detail.

ABRAMS: I appreciate you submitting your question in advance, because it did give me some time to think about it.

I think the thing that may not be totally clear is that this new program began March 1, 2014. So, we don't have much data yet.

We're not quite two months into it.

What we are very proud of, and I congratulate all of our NCTN groups for achieving, is we had a switchover on March 1 of all of our IT systems. This was a rather major undertaking, because not only do we have the trials that are currently active, but we also had a large legacy load of trials, and all the patients on those trials to move over to this brand-new IT system.

We accomplished that.

There have not been major glitches, at least not that I'm aware of. We have now moved into a system for the very first time in over 60 years, where every single enrollment in a clinical trial on the NCTN will be captured in real time centrally.

So, going into the future, I hope we will be able to provide much better data about the number of patients on our trials, about the types of trials.

But I will tell you that much of the information that is already available on the Cancer Trial Support Unit public website, where anybody can go on that website and they can look at the trials that are going on in every disease, the numbers that are anticipated to be enrolled in that trial, and the numbers of patients actively enrolled

at present in that trial.

And that information is currently available to anyone.

BANGS: I think there may be a misunderstanding relative to my question.

My question has to do with the vision we're implementing based on the IOM report, the key measures of success, where we are in relative to those goals. Whether we are at two months or not, the IOM report was published several years ago, we are charting a path, so I would like to understand where are we in that path, what are the opportunities left that we need to address, so that we can understand where this is taking us?

I think this requires a more detailed response. You answered a different question than I asked.

ABRAMS: OK, so I understand a little bit differently what you intended now.

One thing that I can tell you is throughout the IOM report, they did talk about back office and front office consolidation of cooperative groups, and streamlining, so I think that the RFA, the new program that we put out did accomplish a streamlining and a consolidation of the networked groups.

It also talked about doing better science, and that was the goal of funding the ITSes, and having the ancillary science program that I mentioned for biomarkers and quality of life. So we have those programs, we have them funded, they are up and running.

In addition, they talked about efficiency. There was a lot of emphasis on efficiency. We have worked hard on bringing efficiency to the system in many different ways.

I'll just name a few of them right now. But we do have a single data capture system for all the sites. The Medidata Rave system, with the help of many in the network groups, has been implemented over the past several years, and is now the way we do our clinical trials.

That's a big improvement over the past, where every group had a different system. In addition, we now have an operational efficiency working group timeline for every single protocol that comes in, whereby phase III protocols have to be implemented within 15 months, and phase I and IIs within 12 months.

That's a major improvement over the way the system used to run.

We have guidelines for closing trials if they are not meeting their accrual goals; we didn't have those in the past, and that's to make the system much more efficient. And finally we have made the central IRB mandatory for all the sites.

About 50 percent of the sites have joined the central IRB. We are giving the rest of the sites about a year to a year and a half to join and make their transition. But in about a year to a half from now, and that is a metric you can we can all look at, we hope that 100 percent of the sites will be in central IRB, which is another big efficiency and time-saver in the system.

So, those are just some examples. It is a very big program, and to go through everything that we have done, it will take more time, but hopefully that is giving you a little bit of an idea about the type of metrics we have been looking at.

MICHAEL KATZ [advocate]: First, Jeff, I applaud what has been achieved, and efficiencies, especially all the times lines that has been specified and the objective criteria for closing trials.

I think that's stuff has been very successful and very doable because all of that stuff just didn't really happen, because there wasn't a deadline, and the NCI was able to get the CIRB turnaround down from three months to one month.

It's fabulous and I hope it stays there as we expand the role of the CIRB.

One of the questions that I submitted relates to the realities of implementing the new system.

I know that I was privileged to be involved in some of the implementation discussion at IOM, and the IOM report and recent NCI discussions referenced the transformation to the new model for conducting government-funded extramural cancer trials.

I would say that successful transformations, like successful trials, define endpoints upfront, with baseline performance measures, setting targets for post-transformation performance. And that has been done, in some cases, with the timelines and that is great.

And the discussions of the new NCORP and NCTN, and the most recent announcements, there are substantial shifts, as we've said, in both overall funding and allocation of funds to various constituents and operational and functional units.

It's not clear that the changes and funding are going to fuel the transformation and how the outcomes are going to be improved. In fact, it's hard to piece this together, because that lack of data, but with the dramatic cuts to critical infrastructure like operations and stats, it's really unclear how current performance levels can be maintained and how we can make good on our commitments to patients that are on existing trials, let enhanced performance.

What I have been told, and it's all anecdotal, which is why I would really love to see facts, is that the levels are being set at points in operations in some of the entities, where the accruals have to be capped below

the level of the current accruals that are occurring in current trials.

So that we won't be able to finish current trials, I'm being told, in some of the entities with the operational and statistical funding cuts, let alone do the new trials that we all hope are going to get done.

It's very frustrating to hear that we can't get this information from the NCI—I don't know whether it's accessible via FOIA, if we're able to run around to the different groups. If NCI could report at an aggregate level, what its expectations are for how many accruals it's going to be funding at an aggregate level for existing trials and for new trials, which would be a good thing.

And if there was a link, to say that it was tied to the funding, that would be great. Because it's not clear that if you cut the funding in the operations section, for example, that you can physically do the work required to do the accruals.

It's different than cutting time frames. I am hoping that you will be able to respond in a detailed way about the functions that are going to make sure that we can meet the commitments that are being expressed for existing trials and new trials.

ABRAMS: We do recognize that we may not be able to enroll, going forward, quite as many patients on clinical trials annually as we have done in the past. In the past couple of years, it's averaged anywhere from 21,000 to 23,000 a year in group trials. This number may have to go down. We've calculated that we can do about 17,000 interventional enrollments and about 2,000 additional patients getting screened for trials, and another few hundred being put on imaging-focused trials. So that number may get us up to close to 19,500.

It would not surprise me—because it's hard to turn the system on a dime—because we obvious have all the older trials that are active that we may overshoot that in this first year and actually have to come up with supplemental funding to ensure that we do support all our active ongoing trials.

So it may turn out that we have somewhere around 20,000 accruals this year, but our program is targeted a little bit lower than it has in the past, because we've added these new components to the system, and we've built a prioritization approach, with our disease-specific steering committees, where every trial that is proposed by a network group gets rigorously evaluated and prioritized in terms of its likely impact on changing the practice in that disease and really helping patients.

Whereas we may not be able to do quite as many studies as we did before, we are hopeful that the studies that we do will be very important ones and very scientifically focused ones. We've ensured the infrastructure to do that.

I should mention that not included in those numbers are the payments for biopsies and specimen collection, and other things that are so important to doing the types of clinical trials in oncology that we want to do.

KATZ: My dilemma as a patient is that I am being told that there are going to be problems meeting the commitments to enrollment to current trials and to opening the trials that have been prioritized by the steering committees.

If NCI is going to meet its commitments and deliver what it says it's going to deliver, it needs to look at this now, because we can't come back and fund this at the end of the year, because by that time the breakage will have occurred.

So I think there is a real need for a prospective, analytical view of this to identify where there can be breakage, and my gut says there is going to be breakage somewhere that we don't know about.

JAMES DOROSHOW: What we are in the midst of doing—because this has to be a partnership with the cooperative groups—we are in the midst of one-on-one meetings with the group chairs and their financial people and their statistical leadership—to go group-by-group, look at the numbers as they exist, and try to understand from both sides what that research budget will support and what it won't support.

We've just begun that process, but we are doing it now, which is about as fast after those awards came out as we possibly could. Because, I agree with you, without seeing from the group perspective what the resources can and can't support, it's hard to know from a system-wide perspective how we will move forward.

NANCY ROACH [advocate]: I am on the Clinical Trials and Translational Research Advisory Committee, where a lot of these things have been talked through. So I have seen a lot of this stuff coming down the pike. When we talked about it in 2011, there was talk of a $175 million budget, and in its infinite wisdom, Congress made some decisions, which I think make that challenging, because the budget now is $151 million.

Can you talk about how you are working with that? I know that there are regulations in terms of allowing flexibility. Are you looking at ways to be flexible? Would it be possible to reduce the per-case reimbursement from $4,000 to $2,000? I know this has been hotly contentious over the years, but maybe in some cases it would be better to do that than to cut the operations budgets. I am just wondering whether you are looking at ways to minimize the impact of that kind of gap.

ABRAMS: That is the reason why would like to have these meetings over the rest of this month of May with each of the groups and their financial officers, and actually look for areas where we and they can show flexibility and creativity.

I would say that when we knew we weren't going to have $175 million, but rather we were going to have $151 million, we did already not fund as many grants as we might have if we had had more money.

For instance, we have funded 30 Lead Academic Participating Sites. We might have funded more if we had more funds. Similarly, we did fund these Integrated Translational Science awards, but we might have funded them at a higher amount if we had more funds.

So we did make some changes in the system from what we had previously anticipated.

I am very hesitant to think about reducing the payments at these sites that accrue a lot of patients, because—as you will remember—that was one of the strongest recommendations of the IOM report. They really felt that the system was going to be in a lot of trouble if we didn't reimburse the research better at the sites around the country.

That's a commitment we'd really like to keep. However, another possibility is—again—not to do quite as many trials as we have done in the past and to make sure that the ones we do are really going to have an impact on patient care.

It is tradeoffs, no doubt about it, when you don't have all the funds that you would have liked to. You have to make tough decisions, but we are going to meet with the groups to discuss precisely how best to do that.

ROACH: If I happen to be the director of NCI, I think I might put a higher priority on clinical research than there is in terms of putting dollars on the table. As a community, if we really want to take on shifting priorities at NCI to put more money into clinical research, who makes those decisions, and what do you suggest? Am I putting you on the spot?

DOROSHOW: Nancy, I love you. What else can I say; right?

Let me just say this: it's not just NCI. NIH is in its most difficult position in easily 50 years in terms of funding levels, in terms of the money we have, and the purchasing power of those funds. If anything, your comment is more difficult than most believe.

The biomedical inflator means that the same amount of money today is not the same as it would buy five years ago. But both Dr. Abrams and I sit on the senior leadership group that has to make decisions across the entire spectrum of things that the NCI supports.

I think there is only one way to say this: there has been an extraordinary amount of pain that every area of the enterprise has experienced, whether it is the most basic of basic research, when you sit at meetings, and people are losing their livelihood, losing their laboratories because we are only able to fund grants at the 10th, 11th, 12th, 13th percentile.

It makes it extraordinarily difficult.

When we can't fund translational research activities at levels that can bring things from labs to clinic in a way that—those are expensive enterprises—and those, clearly, have suffered. Every effort has been made to try to get the most with what we have.

I do have to emphasize—I give credit to Dr. Varmus—because, truly, of all of the large programs across the entire NCI—and there are several that are big, programs of over $100 million a year—it's the clinical trials programs that did not actually have to be cut as a consequence of the sequestration last year. And those are the only major, large programs that weren't cut.

I think that shows he is committed to getting things to patients, and taking advantage of all the wonderful basic science that's going on.

The answer to your question is, these decisions are made jointly across the entire leadership of NCI.

ROACH: Well, you know what I think. So, take it for what it's worth.

BARBARA LESTAGE [advocate]: I was watching a CTAC presentation last month, and I was appalled to hear that there is a 25 percent failure to accrue rate in adult trials, and trials close because of this, and given the enormous amount of time and money that it takes to get a trial from development of a concept within a group to open to accrual, we are wasting millions of dollars.

I applaud your streamlining of the system, but since concepts start in the groups, and then by the time they are actually presented to the steering committees, I have found it hard, in my steering committee, to ask questions about what they have done to assure that they will be able to accrue the number of patient they need.

I wonder if there is something you can do starting back in the groups and going all the way through the steering committees until the final funding is awarded to do our best to make sure that we are able to accrue to those trials.

ABRAMS: You are right that we do not want to see trials that a lot of time and effort has been put into, and patients have joined, and then don't meet their enrollment goals. We have to do more, and we've recognized that.

We've spent a lot of time recently working on

moving a trial quickly from its scientific concept to actually opening. Now we are going to shift our emphasis—now that we have timelines for that first stage—to working on better strategies on how to enroll, looking fro trials that may be excellent scientifically but may be hard to do, and work on strategies to improve enrollment.

Fortunately, in each of the network groups, we have a lot of patient advocates, we have people who are trained in this field, and we have now people trained at NCI in this field, who are willing to work as a team to come up with better strategies to improve the results of this trial.

And I am pleased to say that one of the first ones you will see roll out with a much better enrollment package will be the new lung map trial that's going to be done by SWOG. I think you will be impressed when you see the work that the professionals have put into making sure that enrollment on this trial is brisk, and that patients across the country are aware of this trial, as well as their doctors.

And we hope to use that type of effort to really improve our other trial efforts as well, to target trials where we think there will be difficulties in enrollment, to try to figure out strategies that will prevent the problems that you talked about.

LESTAGE: I am very glad to hear that, and I know when I was an advocate at ACRIN, they were extremely welcoming of our comments about the ability for trial to accrue. Unfortunately, I've heard from other advocates in other groups that they are not quite so successful in being able to provide that sort of information.

One of the things I would ask that you might look at the review sheets that we use when a concept comes in to a steering committee and see if there might be some questions added about what they have done to research the ability of the trial to accrue.

ABRAMS: Good suggestion. We do have something along those lines, but we will look into that.

PATTY SPEARS [advocate]: I really want to reiterate that what Mike said and what Nancy said is just crucial. The cuts that have been made to Ops and Stats are going to impact what's going on now and what we can do in the future.

To say that we are going to maintain the trials that are ongoing is great to say, but I am not sure that's going to be really reasonable without new trials going forward.

I think that's the thing that's going on right now because of the cuts.

What Nancy said about the cut in funding—you thought you were going to get an extra $25 million and you didn't—and yet you are still going through with the LAPS, you are still going through with the big initiatives, the MATCH, ALCHEMIST, so it doesn't seem like you've done a lot to mitigate that loss of $25 million.

Putting that in perspective, things are happening, and it's not fun, and it's not good, and it's not going to be good for patients in the long run. I think there are going to be fewer trials available. And then the accrual question was really apropos, because I think in your operations is where that accrual happens, where your patient advocates are is in the operational part of what's going on in the clinical trial network.

And so, by cutting that, you are cutting the things that we've gotten going, some things at the Alliance that are getting cut because of the operation cut. Because when you cut operations, you actually cut people, and those people are the ones running our accrual task force. So, it sounds good on paper—things had to change—and I think what has changed has been really good—the central IRB, keeping an eye on accrual is something that we've long wanted—but these things that have just come down the pike have everybody in the little tizzy, because there are things happening right now, and it is real.

ABRAMS: I don't, by any stretch of the imagination, diminish the discomfort and difficulty in managing the tight budget. We recognize that this budget is going to require difficult decisions on the part of the leadership of the groups.

That's why we want to have meetings with them, try to look for areas where we can be flexible and where they can be.

The other thing that I will mention that I am hopeful will enable us to continue in the whole system to do good research is that this may impact groups differently.

Some groups may have a lot of trials active right now. Some groups may have fewer. Since the patients can go on any group's trial, and the physicians can participate in any group's trial in the new system, we may have to look for those groups who have more capacity while the groups that have more active trials finish up those trials before launching new ones.

We are willing to work with all the group chairs on these approaches so patients in each disease area have important trials to participate in, as do the physicians and we use the capacity of the entire system optimally to get us through this tight budgeting crunch.

SPEARS: And, a follow-up on that, just because a lot of things have changed with the different funding mechanisms, and the LAPS is a big part of it, and

there is not a lot transparent about that. Who are the LAPS? I know they have been notified, and different announcements have come out. What is that funding used for in the lead academic institutions?

ABRAMS: Unfortunately, since there are 30 of them, these grants are going out as we speak, but it will take a little bit longer for every single last one of them to go out.

I think pretty soon we will have all of them out, and we will be happy to publish all the names of the LAPS and make that very available to everybody. They are some of the major cancer centers throughout the U.S.

But we will make that more transparent to people. Because of out grants process, it's not been as available as you would like. We'll certainly move to do that.

RICK BANGS [advocate]: I am interested in hearing what the engagement plan is with the advocates to move this forward from a policymaking perspective as well as getting the facts on the table?

DOROSHOW: In addition to the individual meetings that we will be having with the group chairs and their financial officers, we will also have a meeting, which Dr. Varmus will attend, of all of their chairs and their financial individuals, together, to talk through some of these issues.

We'd like to have those conversations before any of this becomes widely disseminated, because there are a lot of facts and figures that everyone has to agree to. We need to know the impact of all of these various things.

I think it will be different from group to group. It will not be a singular response. It will probably require multiple different responses to try to enhance what the overall network can ensure, what the network can do based on the various circumstances that each of the groups is in.

BULMAN: We will continue to be a conduit for you and the rest of the advocacy community and make material and information available to you, and post it through our listserv and on cancer.gov. I know in earlier discussions we talked about how this is a lot of information, and charts or some sort of grid would be helpful, and we've certainly heard that from you.

We are in the process of pulling together information, and working with pour communications folks here at the institute to help communicate some of the key points of this, and we will continue to do that and get that out to you when we can.

BANGS: This is to reiterate. I think we need to hear what the policy engagement model is with the advocates, what policies and decisions can we be a part of, and I would respectfully point out that we are behind the 8 ball on this, and we must move with due haste. These are retroactive budget decisions that are being made here.

BULMAN: The institute has a policy of sharing information when it is publicly available as soon as we can. I don't know whether policy decisions have been made retroactively. I know that advocates were involved in the CTWG and the IOM report, and there is advocate representation on CTAC and our other advisory boards. That's where a lot of our programs are discussed and policies are proposed. I am not sure I am addressing your question…

BANGS: No. I am just going to give you one example. It's come up several times in this call. We are going from a large number of accruals—close to 30,000—down. That has implications on strategy. Those are policy decisions that the advocates should have a voice at the table.

I am just using that as one example. I think we need to hear specifically from the NCI what role you would like to have the patient advocates play as we are working through this recalibration of the budget. We've earned a place at the table, and I think we need to be specific about what place at the table we really have in this process.

BULMAN: I think there are opportunities to engage through the NCTN working group strategy meetings. Advocates are included in the steering committees that review select phase II and phase III clinical trials concepts.

And in terms of how you work with your individual group that is a party of the NCTN network, that is dictated by the group and how they engage you in their decisions about what trials they want to prioritize.

ABRAMS: One point I'd like to add—because not everybody would know about this; some of the people on the call actually participated in this—but over the last year and a half we had multiple meetings of the NCTN working group and the CTAC subcommittee to advise NCI on how to prioritize, since we knew that we wouldn't have enough funding to have quite as many enrollments as we had previously.

We asked for advice, and advocates took a prominent role in those meetings, and in making suggestions to us about how we should form review bodies to help reach that.

We are going to make a full presentation of this in July, at the upcoming CTAC meeting, and that will be made more broadly available to the advocacy community. We already began a pilot where we try to understand if we had many large trials proposed by the

NCTN groups and we couldn't do them all, how would they advise the review or evaluation group prioritize among these different large trials.

This is a challenging thing for us. We'd, of course, like to do all the trials, but if we are forced to choose for budgetary reasons, we've been working hard to figure out the best evaluation process.

CINDY GEOGHEAN [advocate]: What can we do as advocates that's constructive in this situation? There is no disagreement that the situation is unacceptable to all of us. And I guess I hope that if there were $25 million on the table, we might not be having this conversation.

I know it's not up to NCI to prescribe or direct what we do as advocates, but is there is something we can do? Because it's not just about priorities. There was a lot of planning that went into this. And now it's kind of stalled as a result of funds.

DOROSHOW: I have to thank you for your participation. I think that for the last 10 years we have really called upon the advocacy community to help us as we planned these changes. And the input has been invaluable.

This isn't just a half-full/half-empty comment. We are going to be able to do, with the resources that we have, some really amazing trials, things that you couldn't even have conceived that we would possibly be able to do when we started the Clinical Trials Working Group.

If you think back even 10 years, we didn't have a single example where a specific mutation is a solid tumor would direct therapy for that disease. It would be in the spring of 2004 that the first evidence that might be the case came to bear.

What you do vis-à-vis your own elected representatives I can't give you advice on. It's not my place. But what I can do is to encourage you to continue your participation, because we have to make the very best use of the resources that we have, and—as Dr. Abrams said—is a difficult thing, but it doesn't mean that it's an impossible thing.

It's still a considerable amount of money, and I believe that there are unique efforts that where NCI can work together with the community to—for example—bring together 20 or 30 pharmaceutical companies to work together with us.

Impossible, in the private sphere, in my view. And that's happening, on multiple levels. And your help in helping us define what are the most important things that we can do as a cancer community are at the heart of how we can move forward in a period when our resources are constrained.

Advocates Request Answers To These Questions in Writing

The questions submitted by the advocates follow:

1.) As the cooperative groups evolved into NCTN, they were told that one of their major metrics for success would be the number of patients each new group accrued to clinical trials. They were also told that NCI expected, perhaps almost demanded, collaboration within the groups. Accruing patients to trials sponsored by other groups would be rewarded, and failure to collaborate would be punished during competitive grant renewal process. NCI funding decisions will significantly lower....even cap....accrual to cancer clinical trials. Since accrual can therefore not really be the metric for group success, how will performance of the four adult groups be judged and evaluated? (submitted by: Jim Omel)

2.) I have been told that one of the new groups will have their funding cut remarkably, perhaps as much as 38% in trial administration expense. This is also the cooperative group with the highest grant review score. How can this be judged as fair, and how can follow-up of clinical trial patients possibly occur with a 38% funding cut? (submitted by: Jim Omel)

3.) How does the old system functionally map to the new system? Are there functions that were once under the 'group' umbrella which are now under the 'LAP' or 'NCORP' umbrellas? (submitted by: Nancy Roach)

4.) The Group awards seemed to truly shock group leadership. Were they informed ahead of time what to expect, in detail? If not, why? (submitted by: Nancy Roach)

5.) What will happen to patients on trials at institutions which either decide not to apply for NCORP funding or are not successful in competing and the next-nearest site is hours away? (submitted by: Barbara Lestage)

6.) Given the enormous expense of time, effort and money getting a trial from the development of a concept within a group to 'open to accrual' and the dismal current 25% failure to accrue rate in adult trials what will be done from first presentation of a concept to an NCI Clinical Steering Committee through trial completion to bring the failure to accrue rate to a more acceptable rate? (submitted by: Barbara Lestage)

7.) What tracking system does the National Cancer Institute have in place to ensure no patient is dropped from a trial or that a trial is closed because of funding not closed for patient safety or because one arm was found superior to the other? (submitted by:

Mary Lou Smith)

8.) How much of your budget do you plan on spending on opening new trials in the next 12 months? How are those trials allotted by Group? (submitted by: Mary Lou Smith)

9.) There are still serious concerns about the transition period from where we are today with clinical trials (29,000 patients in 2013) and where we want to be (17,000 patients in 2014). Is there a plan, or actually a time-line? It appears quick decisions are being made within groups without much planning or guidance…. Is the expectation to cut trails ASAP? To stop development on new trials? Will there be a lull in the approval of new trials? (submitted by: Patty Spears)

10.) The IOM report and recent NCI discussions reference transformation to a new model for conducting government-funded extramural cancer clinical trials. Successful transformations, like successful trials, define endpoints up front, specifying baseline performance and setting targets for post-transformation performance. In the discussions of instantiation of the new NCORP and NCTN, there are substantial shifts in both overall funding and allocation of funds to various constituents and operational/functional entities. It is not clear what the changes are beyond changes in funding that will fuel this transformation, how outcomes will be improved and by how much. In fact, with the dramatic cuts to critical infrastructure like operations and stats, it is unclear how even current performance levels can be maintained, let alone enhanced performance. What are the changes to the operating model, to policies, or other aspects that will bring us to a "new system" that will be able to deliver improved performance with flat and/or reduced funding? What is the analytical basis for the funding changes and what is the expected impact on key performance measures (e.g., accruals, successfully-completed trials, practice-changing trials)? (Submitted by: Mike Katz)

11.) As a survivor and as an advocate on behalf of the ultimate end-users of this system, I would really like to see the financial and clinical facts laid out in straightforward fashion. The public has gotten snippets and rumors describing what is happening, but no comprehensive view. We should all have a matrix of numbers that could tell the tale. Ideally, the matrix would show present and new funding for each of the entities covered by the NCTN and NCORP programs. It should also show other key performance measures and explicit quotas, such as patients currently enrolled in trials under treatment and in post-treatment follow-up. Also relevant would be number of new accruals for the period, number of open trials by disease site, and whatever else makes logical sense and/or was used in making the most recent round of funding decisions. In this matrix, the entities would be the columns and the funding components would be the rows. This would go a long way to bringing transparency to this critical transformation. Is this something that is reasonable to expect and, if so, what is the timeframe in which this data can be released? (Submitted by: Mike Katz)

12.) I am led to believe that a number of institutions (e.g., Penn, Northwestern, Fox Chase, Montefiore, CINJ) that previously had their participation funded by U10 grants are no longer to receive those grants and not selected to receive LAP grants. Is there an explicit intent to shut down their participation, as they each have multi-site networks that were accruing and underwriting the requisite infrastructure with the U10's. If so, what is the intent as far as patients currently on study? What was the composition of their new accruals as far as disease sites and underserved populations? Are there any disproportionate impacts and is there an expectation that the "slack" will be picked up by other institutions? (Submitted by: Mike Katz)

13.) Transformations are discontinuities and as such, require deliberate planning to ensure an orderly transition. When implementation was discussed at the IOM NCTN Implementation Workshop, NCI stated that it understood the challenge and recognized that there was a cost to the transition and that it would budget funds to cover the costs of an orderly transition. There appears to be a lack of planning and lack of lead time that could make an orderly transition impossible. With funding changes being announced months after their effective dates, i.e., budgets being cut retroactively instead of being phased in prospectively, the NCTN participants are starting off in the hole financially and not being given time to reconfigure their resources in a controlled manner. Has NCI looked at the impact of these cuts and the timing of these cuts on patients and on the science? How many patients on current trials find their trials terminated for lack of funding? How will the number of new trials be impacted? How will accrual to existing and new trials be impacted? How will the impact be felt in specific disease sites versus overall across the network? (Submitted by: Mike Katz)

14.) What changes in process or outcomes have NOT been achieved to date versus original NCTN vision, what the Key Performance Indicators being used to monitor progress are, and what our results to date are. (Submitted by: Rick Bangs)

15.) With regard to "changes in funding," we

need to see simple comparisons between 2014 budget and the prior actuals by budget element (grants such as NCTN admin grants, NCTN statistical center grants, NCORP grant, and LAPS grant) and major subcomponents. Prior actuals should include 2013 at minimum but would ideally go back 3 to 5 years. This will allow the necessary transparency. This seems simple but probably is not. (Submitted by: Rick Bangs)

16.) For proposed changes between 2013 and 2014 grant years, a rationale for the direction and magnitude of change should be provided. What changes in process or outcomes have NOT been achieved to date versus original NCTN vision, what the Key Performance Indicators being used to monitor progress are, and what are our results to date? (Submitted by Rick Bangs)

17.) If the plan was to complement/integrate with NCTN funding decisions/cycles, why wasn't a strategic decision made to shift the NCORP peer reviews and funding cycles to coincide, or to overlap with NCTN awards? Any "overlap" in funds from June 1 to September 1 could serve as "bridge funding" to accommodate patients and centers who may not transition into the new system. (I don't know what is required to move Study Sections and Peer Reviews but it would have made sense strategically, and would help explain where the money will come from to honor Dr. Varmus' commitment in his Letter to the Community that every patient will continue to be served). It would also demonstrate efficiency on the part of the NCI to streamline reviews and administration. (Submitted by Cindy Geoghegan)

On Biomedical Malthusianism

Paper: Rush to the Clinic Is Not Beneficial to Science

(Continued from page 1)

The paper is important because it comes out at a time when Varmus's restructuring of NCI is taking physical shape. By spelling out what's wrong with the existing system, Varmus may be pointing to the strategic underpinnings of changes he is bringing about at NCI.

One of the most intriguing statements in the paper cautions against overvaluing studies that aim to change medical practice. The statement is interesting—and may be telling—because it is published at a time when NCI is dramatically reducing the number of participants in its clinical trials (The Cancer Letter, Feb. 28, April 4, April 11).

"One manifestation of this shift to short-term thinking is the inflated value that is now accorded to studies that claim a close link to medical practice," the authors write. "Human biology has always been a central part of the U.S. biomedical effort. However, only recently has the term 'translational research' been widely, if unofficially, used as a criterion for evaluation. Overvaluing translational research is detracting from an equivalent appreciation of fundamental research of broad applicability, without obvious connections to medicine. Many surprising discoveries, powerful research tools, and important medical benefits have arisen from efforts to decipher complex biological phenomena in model organisms. In a climate that discourages such work by emphasizing short-term

goals, scientific progress will inevitably be slowed, and revolutionary findings will be deferred."

In addition to Varmus, the authors of the paper are Bruce Alberts, Department of Biophysics and Biochemistry, University of California, San Francisco; Marc Kirschner, Department of Systems Biology, Harvard Medical School; and Shirley Tilghman, Department of Molecular Biology, Princeton University.

The authors argue that the fundamental flaw can be attributed to "the discipline's Malthusian traditions."

Since much of research in the U.S. is conducted by graduate students and postdoctoral fellows, successful scientists train more scientists than would be needed to replace themselves.

"In the aggregate, the training pipeline produces more scientists than relevant positions in academia, government, and the private sector are capable of absorbing," the authors write. "Fundamentally, the current system is in perpetual disequilibrium, because it will inevitably generate an ever-increasing supply of scientists vying for a finite set of research resources and employment opportunities."

Whether young or seasoned, scientists are engaged in an escalating competition for resources.

This is prompting them to starting to think conservatively. "The system now favors those who can guarantee results rather than those with potentially path-breaking ideas that, by definition, cannot promise success," the authors write.

The cautionary statement about excessive emphasis on publication in high-impact journals has been consistently a part of Varmus's opening remarks at meetings of NCI advisory boards.

The PNAS paper reflects this point as well:

"As competition for jobs and promotions increases, the inflated value given to publishing in a small number of so-called 'high impact' journals has put pressure on authors to rush into print, cut corners, exaggerate their findings, and overstate the significance of their work. Such publication practices, abetted by the hypercompetitive grant system and job market, are changing the atmosphere in many laboratories in disturbing ways. The recent worrisome reports of substantial numbers of research publications whose results cannot be replicated are likely symptoms of today's highly pressured environment for research. If through sloppiness, error, or exaggeration, the scientific community loses the public's trust in the integrity of its work, it cannot expect to maintain public support for science."

The Model: NCI Intramural Program

The paper's recommendations include greater reliance on staff scientists.

"There is precedent for such a policy in the intramural NIH research program, which employs many well-trained MSc and PhD graduates as staff scientists to conduct research," the paper states.

This recommendation is noteworthy, because NIH recently launched an examination of its intramural program (The Cancer Letter, March 7).

NIH-wide, the intramural program accounts for 11.1 percent of its $30 billion budget. At NCI, the budget authority for intramural research accounted for about $869 million in fiscal 2014, about 17 percent of the institute's overall spending.

Intramural research is separate from contracts. NCI's largest contract involves running the Frederick National Laboratory for Cancer Research, which receives about $300 million a year. This amount is expected to increase during the current fiscal year (The Cancer Letter, Feb. 28).

In the past, the contract, which is administered by Leidos Biomedical Research Inc.—formerly named SAIC-Frederick—was often used by NCI directors to fund projects they didn't want to submit to peer review.

Now, Varmus is aligning the newly designated national lab administered by Leidos with the institute's scientific mission. He has formed an advisory committee to guide the national lab, and the lab is one of the few NCI programs to get a raise (The Cancer Letter, Feb. 28).

The lab's projects include the RAS program. Recently, Leidos officials published informational videos describing the mission of the lab.

The NIH intramural program was last examined in 1993, pursuant to a mandate from the House Appropriations Committee.

That examination was written by a panel co-chaired by Paul Marks, then-president of Memorial Sloan-Kettering Cancer Center, and Gail Cassell, then-chair of the University of Alabama Department Microbiology.

The Marks-Cassell report recommended uniform, rigorous reviews of intramural scientists and tying promotions and resources to scientific merit. Just as importantly, the report called for consultation with extramural researchers in setting the parameters for the NIH intramural program.

"In the context of these recommendations, a centralized decision-making process governing the total NIH extramural/intramural allocation should

ensure that the total intramural research program budget for institutes, centers, and divisions does not exceed the current rate of 11.3 percent of the total NIH budget," the Marks-Cassell report recommended.

Marks is president emeritus of Memorial Sloan Kettering Cancer Center and member of the Sloan Kettering Institute. Cassell is a now a senior lecturer on Global Health and Social Medicine at Harvard Medical School.

Relying on Staff Scientists

According to the paper, laboratories in the U.S. haven't relied on staff scientists, in part because they command higher salaries than trainees and postdocs.

"These arguments ignore the fact that beginning graduate students and fellows are also costly because they often require considerable time to become highly productive," the paper states. "We believe that staff scientists can and should play increasingly important roles in the biomedical workforce. Within individual laboratories, they can oversee the day-to-day work of the laboratory, taking on some of the administrative burdens that now tend to fall on the shoulders of the laboratory head; orient and train new members of the laboratory; manage large equipment and common facilities; and perform scientific projects independently or in collaboration with other members of the group. Within institutions, they can serve as leaders and technical experts in core laboratories serving multiple investigators and even multiple institutions."

To make this change work, universities would have to create a career path for staff scientists and granting agencies would need to learn to value the contributions of long-serving lab members. "Two of the likely consequences of these changes in graduate and postdoctoral training and employment of staff scientists will be an increase in the unit cost of research and a reduction in the average size of laboratories, the paper states. "We believe that the significant benefits—including brighter prospects for trainees, less pressure to obtain multiple grants to sustain a group's financial viability, increased incentives to collaborate, and more time for investigators to focus on their science—substantially outweigh the limitations."

The paper's other recommendations include:

• Plan for Predictable and Stable Funding of Science.

Congressional appropriators and the executive branch should consider adding a five-year projected fiscal plan. "This plan would be updated each year, at the same time that annual appropriation bills are written," the paper states. "This modest addition to the present system, while not creating inflexible mandates, would acknowledge the need for long-term planning for measured growth of the nation's scientific enterprise."

• Gradually reduce the number of entrants into PhD training in biomedical science.

"To give federal agencies more control over the number of trainees and the quality of their training, we propose moving gradually to a system in which graduate students are supported with training grants and fellowships and not with research grants," the paper states.

"Fellowships have the virtue of providing peer review of the student applicants, and training programs set high standards for selection of students and for the education they receive. If this recommendation is adopted, it will be essential to change policies that now prohibit the funding of non-U.S. citizens on training grants."

• Broaden the career paths for young scientists.

"We should aim for a future in which graduate students have opportunities to explore a variety of career paths, with only those seeking careers that demand additional research training taking up postdoctoral research positions," the paper states.

"To that end, the NIH has recently announced a new program to encourage diversifying graduate education. Moreover, interdisciplinary MS degree programs that combine training in science with leadership, project management, teamwork, and communication skills match well with industry needs and should be expanded with federal support."

• Reduce the number of biomedical research postdoctoral fellows from the current U.S. level of 40,000.

i) "Increase the compensation for all federally funded postdoctoral fellows, regardless of grant mechanisms. This would need to be done gradually over time, with the goal of reaching the compensation levels for staff scientists.

ii) "Limit the total number of years that a postdoctoral fellow may be supported by federal research grants. Beyond this limit, salaries would be required to rise to that of research staff scientists."

• Improve the goals and mechanisms for scientific grants.

i) "We recommend wider use of grant mechanisms that provide more stable support for outstanding investigators at various career stages, focusing as much (or more) on the overall quality of their science as on their proposed projects.

ii) "Sunset provisions should be built into all new programs and orchestrated team efforts. To combat the tendency for fields to become parochial, agencies should develop funding mechanisms that encourage the growth of new fields, both by direct support for new science and by a rigorous regular evaluation of existing programs.

iii) "Science agencies should significantly increase the numbers and kinds of awards that emphasize originality and risk-taking, especially in new areas of science, without requiring extensive preliminary results.

iv) "Agencies should be sensitive to the total numbers of dollars granted to individual laboratories, recognizing that—although different research activities have different costs—at some point, returns per dollar diminish. For that reason, we applaud the recent decision by the NIH to examine grant portfolios carefully before increasing direct research support for a laboratory beyond one million dollars per year."

• Improve evaluation criteria.

i) "The qualitative aspects of each candidate's major scientific achievements should receive more emphasis than the numbers and venues of publications. Evaluation criteria should also put a higher priority on the quality, novelty, and long-term objectives of the project than on technical details.

ii) "Review guidelines should be appropriately adjusted for young scientists to promote the funding of thoughtful proposals that reveal ingenuity and promise findings with potentially broad implications."

• Strengthen grant review panels.

i) "The quality of review groups should be enhanced by taking advantage of the full range of talent in the scientific community. All current grant holders should be expected to serve on such groups if asked and not just once in a career. In addition, federal agencies should diminish the requirement for geographical representation that now limits the choice of panel members.

ii) "Those who plan and assemble review groups should broaden the range of scientific problems judged by each group and include a diversity of fields on each panel. Senior scientists with a wide appreciation for different fields can play important roles by counteracting the tendency of specialists to overvalue work in their own field."

• Evaluate programs, policies, and their implementation.

"We urge agencies to continue and expand such evaluations, to make the findings publicly accessible, and to recognize the advantages of having them performed by groups that are independent of the agency being examined. The questions asked should include whether a particular program or policy is being well executed, how it might be improved, what types of data are needed to guide evaluation, and whether the goals might be better met in other ways."

• Address Questions of Indirect Costs.

"Federal policies regarding indirect cost recovery have also enabled academic medical centers and other institutions to expand their faculties and facilities without making corresponding investments of their own, generating some of the perverse incentives discussed earlier.

"We recommend that the U.S. government develop a plan to revise these practices gradually over the next decade while providing a discrete timetable. Targets of policy change should include the full reimbursement to amortize loans for new buildings, the payment of indirect costs on faculty salaries, and the provision that allows 100% of faculty salaries to be supported on research grants."

In Brief

Morris Leaves MD Anderson

(Continued from page 1)

Morris will provide financial and operational leadership for DiabetesAmerica's locations in Texas. His last day at MD Anderson will be June 6.

In a note to faculty and staff, Leon Leach, MD Anderson's executive vice president and chief business officer, wrote:

Dwain joined MD Anderson as director for enterprise reporting in 1999 and became chief financial officer in 2008. During his tenure, the institution grew exponentially, from total operating revenues of $930 million in Fiscal Year 1999 to nearly $4 billion in FY13.

He guided MD Anderson through our first external financial audit, and established a practice of annual external financial audits that set a gold standard for other UT System institutions and served as a model of responsible financial stewardship across all Texas state agencies.

He put into practice transparent methods of sharing financial information because of his belief in the importance of two-way communication and in educating all employees on how external and internal factors come together to impact us.

Dwain has built a strong team of professionals

who are extremely knowledgeable and dedicated and will ensure the operational and strategic financial activities continue to move forward. These folks will report directly to me while we conduct a search to fill the CFO position.

Dwain has been an integral member of the institution's executive team. His leadership and expertise has helped MD Anderson maintain a strong financial position and positioned the institution for financial stability in the coming years.

I want to thank Dwain for his years of service to MD Anderson. We're sorry to see him leave, but know that he'll be tremendously successful in his new role. Please join me in extending him thanks, congratulations and best wishes.

THE NATIONAL ACADEMY OF SCIENCES elected 84 new members in recognition of their achievements in original research. The academy also elected 21 foreign associates from 15 countries. Foreign associates are nonvoting members from outside the U.S.

This brings the total number of active members to 2,214, and the total number of foreign associates to 444. Approximately 200 have received Nobel prizes.

Consideration of a candidate begins with his or her nomination, followed by an extensive vetting process that results in a final ballot at the academy's annual meeting. A maximum of 84 members may be elected annually.

A full list of the newly elected members is available on the academy's website.

THE DEPARTMENT OF DEFENSE Peer Reviewed Cancer Research Program is offering $25 million to support innovative, high-impact cancer research. This program is administered by the US Army Medical Research and Materiel Command through the Office of Congressionally Directed Medical Research Programs.

FY14 PRCRP program announcements and general application instructions for the following award mechanisms are posted on www.grants.gov.

The topic areas include: blood cancers, cancers related to radiation exposure, colorectal cancer, genetic cancer research, kidney cancer, listeria vaccine for cancer, melanoma and other skin cancers, mesothelioma, myeloproliferative disorders, neuroblastoma, pancreatic cancer, and pediatric brain tumors. Cancers related to radiation exposure and myeloproliferative disorders are new for 2014.

Investigations into cancers related to radiation exposure should include research directed to improve the understanding of elevated cancer risk among military service members exposed to increased levels of ionizing radiation including: modulation by host factors, occupational and environmental exposure, assessment of risk among active duty and veterans, routes of exposure, and dose and risk estimates.

Studies within the scope of myeloproliferative disorders as defined by NCI will be accepted.

Applications that address exposures, conditions, or circumstances that are unique to the military, or disproportionately represented in a military beneficiary population, are the highest priority, though any applications that address the above focus areas will be considered.

Investigators are strongly encouraged to collaborate, integrate, and/or align their research projects with Department of Defense and/or Department of Veterans Affairs research laboratories and programs.

The Career Development Award supports an independent investigator at the level of assistant professor, instructor, or equivalent within seven years of first faculty appointment at the time of application deadline to conduct innovative research with the mentorship of an experienced cancer researcher.

Preliminary data is not required and clinical trials are not allowed. Maximum funding for the entire period of performance is $360,000 in direct costs (plus indirect costs) for a maximum period of performance of three years.

Pre-application due June 10, with letters of invite issued in July, and full applications due Sept. 17.

The Idea Award with Special Focus supports an independent investigator at or above the level of assistant professor, funding innovative, untested, high-risk/potentially high-reward concepts, theories, paradigms, and/or methods in cancer research that are directly relevant to service members, their families, and other military beneficiaries

Preliminary data is discouraged and clinical trials are not allowed. Maximum funding for the entire period of performance is $300,000 in direct costs (plus indirect costs), with a maximum period of performance of two years.

Pre-application is due June 10, with letters of invite issued in July, and full applications due Sept. 17.