

**NWX NCI**

**Moderator: Jennifer Kwok**  
**May 16, 2014**  
**3:24 pm CT**

Operator: Welcome and thank you for standing by, at this time all participants are in a listen-only mode. After the presentation we will conduct a question-and-answer session.

To ask a question please press Star then 1 and record your first and last name, to retract your question please press Star then 2. Today's conference is being recorded, if you have any objections you may disconnect. I would like to turn the meeting over to Ms. Amy Bulman, thank you and you may begin.

Amy Bulman: Good afternoon, hi everyone this is Amy Bulman calling from the National Cancer Institute.

Thank you so much for joining us today we appreciate your patience and apologize for the delay in getting started. I can assure you that there's not a fire here in the building where we are today but we did have to go through that exercise to ensure there is not, so we very much appreciate your patience. Many of you we've spoken to individually and in small groups over the past couple of weeks about our clinical trials portfolio here at the National Cancer Institute and that's what we're here to talk a little bit more about today.

We very much appreciate your willingness to engage with us and your interest and expertise with this issue. So we're here this afternoon to talk a little bit about (Intec)'s clinical trial program, namely the National Clinical Trials Network, NCTN as it's often referred to and NCI's NCORP, Community Oncology Research Program.

We wanted to give everyone an opportunity to hear from our NCI experts that work with these programs to talk a little bit about what we've been up to, where we're coming from and where we're headed. So this call will basically have two components, the first will be remarks and comments from our NCI leadership. You'll hear today from Dr. Jim Doroshow who is our Deputy Director for Clinical and Translational Research here at NCI.

Also you'll hear from Jeff Abrams who is our Director for Clinical Research and also Dr. Wortia McCaskill Stevens who is our director of NCI Community Oncology Research Program. So I think most of these researchers are familiar to you. Dr. Doroshow will start us off and then we'll hear from our other two speakers and then we'll open up the line for some questions. I know that we've received a number of questions from you in advance of this call and we very much appreciate that.

We look at this at the beginning of a dialog and we wanted to have an opportunity to engage with you today and answer some of your questions, so we will leave time for questions. We realize that we're starting a little late so we will - but we are able to give this call the full 60 minutes that we originally planned, we've extended the line for that time so that we'll have time for both comments and questions. So with that I'll turn it over to Dr. Doroshow to kind of get us started, thanks so much.

Jim Doroshow: So thanks very much Amy and thanks to all of you. There are many of you on the phone, thanks for taking the time to have this dialog with us.

As a large number of you already know the clinical Cooperative Groups Program at the NCI is one of the longest standing programs being over - well in a year or two it will be about 60 years old, a major effort that has really changed the face of clinical oncology and clinical oncology practice over that time.

It's not that much younger but it's also a critically important component of the National Group Trials Program is our CCOP and MBCCOP Program, it's also been effectively bringing, you know, clinical trials to the community for several decades. And so we're very pleased to have Wortz here to help us understand the changes that are going on in that program.

I think that the first thing that I have to say to you is that many of you actually who are on this call and some were probably not, but in fact I think there are several on the call have actually participated with us for what is now a ten-year process in trying to move the clinical trials activities of that the NCI supports forward. This process has involved extensive consultation with the (extramural) community, with our national advisory boards.

I'm in the development of multiple written reports providing us with goals in terms of trying to make the programs better. Those are those in clinical trials working group report, the operational efficiency working group report, the really seminal report from the Institute of Medicine about our cooperative group system that has helped guide us in terms of making changes as the system has moved forward.

We are absolutely committed to having the most effective, efficient clinical trials program that the government can support. And let me just give you a word or two about -- for those of you who haven't perhaps read all of those reports -- some of the guiding principles that we've gone by over the last ten years. We've tried to think about with our constituents both scientific and advocacy constituents how we can do clinical trials more effectively.

How we can modify the system that we have to reflect the remarkable changes over the last 10 to 15 years in oncologic science - tumor biology, genomics, molecular pharmacology that have really transformed how we think about treating patients with cancer. And our goals have always been to try to develop a way to put together a network of our organizations that could allow us to utilize those important and sometimes expensive tools of molecular biology to find the best trials that we'll utilize and be available to patients.

That really has been a very major paradigm shift in terms of how we go about thinking about doing clinical trials. We needed to have a system that would allow us somewhat differently than 15 or 20 years ago to actually reach a very large number of patients across the United States who could be screened for molecular abnormalities that might facilitate their response to various treatment types that we would go forward with.

That's really somewhat different than we had run this program in the past and it's been one of the guiding principles. A second principle pointed out by many, many colleagues across academia from (pseutical) industry and advocacy once try to make our system as efficient operationally as possibly so that we open trials quickly and accrued - accrue to those trials and quickly and that has meant working together with many, many working parts of this system to try to make improvements.

Substantial improvements have been made and documented and that has only been possible because so many of you who are on the call and others have worked together with us to try to do that. And so I think lastly I'd like to point out that it has been now at least three years, perhaps four that we've been thinking about in the context of the changes for the overall MPtM how we might better integrate those kinds of studies into the community.

And furthermore how we could do a broader range of studies in the community, not simple cancer prevention trials or cancer treatment trials which remain central to what we want to do but also to understand how the practice of oncology is changing and how we might assist in making those changes known and evaluate what those changes are and how effective they have been.

And so it's now some years that we have worked together both the Division of Cancer Treatment Evaluation and the Division of Cancer Prevention to try to think through how our community program could both (intricate digitate) at the cutting edge of molecular precision medicine and also in the area of health research evaluation types of research. And that's been an important effort that has involved both divisions and our community partners.

And so I think we've made significant progress in moving toward that combined effort so that really the NCI is supporting the broadest range of clinical (interventional) activities that will assist patients from everywhere from a specific molecularly driven trial to understanding how we implement those new treatments in the context of the broader community. And I'm very pleased to be here and I hope that we'll have time to ask - answer as many of your questions as possible.

And so I'd like to hand it over now to Jeff Abrams to talk about some of the new components of the NCTN.

Jeff Abrams: Thank you Jim and good afternoon to everybody. The new system - and it is really new, I mean as you just heard the cooperative group system has been in existence for a very long time.

But in NCI (grantsmanship speak) this was a brand new competition, it was just the old groups did not exist and they had to re-compete as entirely new entities. And one of the recommendations that we receive from many advisory boards is that we needed to perform a consolidation. So NCI had said that we would fund up to four adult groups and one pediatric group. And that's exactly what happened, we consolidated down to a total of ten groups to five groups.

And each of these groups has an operations and statistical component in order to perform their clinical trials. Now other new components of the system that have changed from before include a new grant to lead academic participating sites. And these grants go to largely academic sites who contribute or at the intellectual (fire power) of the groups. In the past there were grants to sites but they were only about 17 of these across the system.

And now in the new approach there were 30 of these, two major cancer centers and major contributors to the cooperative - to the new NCTN system. In addition there's a new award called the integrated translational science award, the (whole peer) was that by teaming the NCTN groups with some leading scientists we would be able to really change the type of trials that we were doing and bring into these trials more of the early scientific findings that are coming out of the laboratories and are very exciting in terms of where the future of oncology should go.

In addition we had several separate quality assurance centers for radiation therapy and for imaging and we had those consolidated into a central core facility. So those changes had to come out of the funding that was available for the system. The overall budget for the entire system is \$151 million. We were very fortunate that this number is what we were able to fund in 2012 and 2013 and this number remained flat in 2014.

Flat is not good, we understand that but compared to many other programs, in fact compared to all the other programs within the NCI this was the only program in 2013 that did not receive a cut in it's budget. Additionally I'd like to just mention that the \$151 million is the support that goes to the entities that I just spoke about, the group (ops and stats offices, the lab). It's the Central Imaging Core, the Canadian group that's part of the program.

But in addition NCI also supports many centralized functions now that help these NCTN programs. These include a cancer trial support unit which is sort of like a one-stop shop for the groups to conduct all their trials. The central IRBs so that we no longer have to go through many hundreds of local IRBs to get each trial approved. We also support tumor banking for each group. We have an ancillary studies fund that's very important to the groups because they're able to support biomarker research and quality of life research out of that fund.

So this money is in addition to the \$151 million that I mentioned previously. I would also like to mention that we knew it was going to be challenging for these long-standing groups, these 10 groups to combine and consolidate. So over the preceding years we have supported them with transition funds so that they could consolidate their statistical offices, some of them their operation's

offices. Each partnership worked this out differently and it was up to them to decide how they wanted to work out these arrangements.

But NCI did provide additional funding to help make those consolidations possible in advance of the re-competition. So, you know, as we go forward we all want to be doing some of the genomically-based trials that everybody's very excited about and that many of the groups are working on and some of you may know of these trials. Some have lung cancer, others adult solid tumors and lymphomas - lymphoma and we are very excited to have this new network that can now perform these trials across all the groups.

In terms of - and I know this is a question on many people's minds so I just want to state it at the very beginning of this call, in terms of closing down trials we're not - that are currently active, we're committed to working with the group chairs to make sure that no act of trial that is accruing appropriately and meeting its endpoints is closed. Those - that's a commitment that we've made to the patients who have participated in those trials, we've heavily invested in those trials and we will work with the group chairs to make sure those trials are carried out.

Whether we will be able to do as many new trials going forward well a lot depends on how the sides of those trials and how the groups work together to enable and - to enable more trials to be done by this collaborative model that we've now developed. So I'm going to stop it here, turn it over to Wortá McCaskill Stevens who will tell you a little bit more about the NCORP.

Wortá McCaskill Stevens: Thank you very much, the NCI Board of Scientific Advisors approved the concept for NCORP in June 2013. Applications from the response from the three FOAs which reflect the components of the NCORP were received in January of this year.

These applications are currently under peer review. It is our goal to issue awards of NCORP on August 1. Until these awards are made NCI will fund all currently funded CCOPs and Minority Based CCOPs at their current level during the transition into the new program. Specifically this transition period includes June 1 through August 1.

Each of the currently funded CCOPs and minority based CCOPs have received instructions for how to obtain funding. NCI is very committed to (include) transition without disruption of patient care. In most cases a patient will continue their care and follow-up at the same institution or site if the organization has successfully competed for NCORP (class). Sites who do not receive NCORP funding may affiliate with a successful NCORP site and continue participating in clinical trials.

Or there's an opportunity to apply for affiliation directly with one of the four adult NCTN groups or other pediatric groups. These sites will need to work with those specific groups to meet the criteria for those perspective groups. NCI will work with those sites that choose not to affiliate with NCTN groups to find NCORP sites at which patients can receive care and continue on clinical trial participation.

If a site needs to close out we will work with those sites on a case-by-case basis to determine the resources and the number of patients that need to be followed on active treatment or active follow-up. This is all consistent with how NCI has supported the continuation of research in the past. For example when (Glen) application has competed for renewal and were not successful, provisions were made for continued care (involvement) at the sites or to provide guidance to these sites for affiliation with other programs to continue their participation.

Just a word about data that has been collected by those who have had participated in clinical trials, these data will not be lost. They are incorporated into the CCOP Minority-Based database and will continue to be a part of the NCORP database - if a patient opts not to continue on the clinical trials that's an option that's a part of the informed consent. I'd just like to say that there - we have a web site for NCORP, it is [prevention.cancer.gov/ncorp](http://prevention.cancer.gov/ncorp) and it is here that you might review the FOAs for the program.

Questions and answers that were submitted to us through the orientation session as well as a slide rack that gives an overall of review of the program. Thank you.

Amy Bulman: Thanks so much Wortz, so at this point I think we're going to move - we want to make sure we have ample time for question-and-answers so I think we'll move into that period of the call. Operator can you give the group instructions for how they can open their line to ask a question.

Operator: Yes, at this time we would like begin a question-and-answer session. To ask a question please press Star then 1 and record your first and last name, to withdraw your question please press Star 2. And one moment please for our first question.

Amy Bulman: Hi thanks so much, this is Amy again. As I mentioned at the beginning of the call we received a lot of questions in advance of today's teleconference.

So while people are queuing up and, you know, queuing up in so that they can ask their own questions we thought it might be a good use of time to kind of go through some of the questions that were submitted in advance. One that we received in multiple ways was around can NCI share peer review scores of

those parties that participate in NCTN? And how is funding related to the review of the components of NCTN? So with that I think I'll turn it over to Dr. Doroshov and Dr. Abrams.

Jeff Abrams: Okay so as far as the funding goes it's a pretty obvious question and I understand everybody 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're free to do that. But we have to treat it as confidential because it is a competition - a scientific competition to get these awards.

Similarly we don't give out peer review scores, we treat that as confidential because that's part of our agreement with the investigators with their application.

Amy Bulman: Thanks Dr. Abrams, so similar or kind of along those lines can NCI share the request and an official budgets for NCTN?

Jeff Abrams: You know, again similarly for the actual awards to grantees as I said the budget for the NCTN's entire program, all it's components is \$151 million in this fiscal year, this year 2014 which was stable compared to last year's budget.

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

Amy Bulman: Thanks, at this point we have a handful of callers that have signaled that they would like to ask questions which is fantastic, so I think we'll move to that. Operator can you open the first question? Rick.

Rick Bangs: Yes this is Rick Bangs from SWOG, I'd like to use Question 14 that was pre-submitted.

So the question is what changes in processor outcomes that's not been achieved to date versus the original NCTN vision? What the key performance indicators being used to monitor progress are and what our results to date are? I don't expect you to give me a detailed answer, that would be impossible on this call. So I'd like to get kind of a general flavor but I'd also like to understand when we would get a written response to that question in detail.

Jeff Abrams: Yes thank, let me -- this is Jeff Abrams again -- let me just explain, you know, I appreciate you submitting your question in advance because it did give me some time to think about it.

I think this thing that may not be totally clear is this program began - this new program that I just talked about began March 1, 2014. So we don't have much data yet, you know, we're two - we're not quite two months into it and the - what we were very proud of and I congratulate all of our coop- our NCTN groups for achieving is that we had a switchover on March 1 of all our IT systems.

This is a rather major undertaking because not only do we have the trials that are currently active but we had a large legacy load of trails and all the patients on those trials to move over into the brand new IT system. We accomplished that, there have not been major glitches, at least not that I'm aware of and we

now have moved into a system for the very first time in over 60 years where every single enrollment on a clinical trial in the NCTN will be captured in real-time centrally.

But going into the future I hope we will be able to provide much better data about the numbers of patients on our trials, about the types of trials. But I will tell you that much of that information fortunately is already available on the Cancer Trials Support Unit public web site.

Where anybody can go on that web site and they can look at the trials that are going on in every disease, the numbers that are anticipated to be enrolled to that trial and the numbers of patients actively enrolled at present to that trial and that information is currently available to anyone.

Rick Bangs: So am I still on - am I still live?

Amy Bulman: Yes.

Jeff Abrams: Yes.

Rick Bangs: Okay so I think there may be a misunderstanding relative to my question. My question has to do with the vision that we're implementing that was based on the IOM report, the key measures of success that we have, where we are relative to that (report).

So whether we're two months or not, the IOM report was published several years ago. We are charting a path, so I'd like to understand where are we in that path, what are the opportunities left that we need to address so that we can understand we are we - where this is taking us. And I think it requires a more

detailed response and the response - you answered a different question than I asked.

Jeff Abrams: Okay so, you know, I do think I understand a little bit different, you know, what you intended now.

And, you know, one thing I can tell you is throughout the IOM report they did talk about back office and front office consolidation of the cooperative groups and streamlining. And so I think that the RFA, the new program that we put out did accomplish a streamlining and a consolidation of the network groups. It also talked about doing better science and that was the goal of funding, the (instances) 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're up and running. In addition they talked about efficiency, there was a lot of emphasis on efficiency and we have worked hard on bringing efficiency to this system in many different ways. I can just - I'll just name a few of them right now, but we do have a single data capture system for all the sites. This 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. (Physician), 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 about closing trials if they're not meeting their accrual goals we didn't have those in the past and that should make the system much more efficient.

And finally we have made the (Central Lyer) be mandatory for all the sites. About 50% of the sites right now have joined the (Central Lyer B), 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 and a half from now and that's a metric that you can - we can all look at, we hope that 100% of the sites will be in the (Central Lyer B) which is another big efficiency and timesaver in the system.

So those are just some examples, it's a very big program and, you know, to go through everything that we've done would take more time. But I think hopefully that's given you a little bit of an idea of the type of metrics we've been looking at.

Amy Bulman: Great, thanks Dr. Abrams, we'll take the next question.

Operator: The next questions comes from (Mike Kays) your line is open.

Amy Bulman: Hi (Mr. Katz).

(Mike Kays): I'm sorry I didn't get the pronunciation of my name - hi, am I alive?

Operator: Yes.

Amy Bulman: Yes.

(Mike Kays): Okay great, thank you, first (Jeff) I applaud what's been achieved in efficiencies, especially with all of the timelines that have been specified and the objective criteria for closing trials.

I think that that stuff has been very successful and very doable because a lot of the stuff really just didn't happen because there wasn't a deadline. And even NCI was able to get the CRAB turnaround down from three months to one month which is fabulous. And I hope that it will stay there as we expand the role of the CRAB. You know, 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 discussions at IOM. And, you know, the IOM report and recent NCI discussions reference the transformation to the new model for conducting government funded (SWOG) cancer trials. But, you know, I would say that successful transformations like successful trials define endpoints upfront with baseline performance, measures and setting targets for post-transformation performance.

And that's been done in some cases with the timelines and that's great. And the discussions of the new and corporate NCTN and the most recent announcements, there's substantial shifts as we've said in both overall funding and allocation of funds to various constituents and operational and functional units. And it's not clear that the changes in funding are going to fuel a transformation and how the outcomes are going to be improved.

In fact, you know, it's hard to piece this together because of, you know, the lack of data. But with the dramatic cuts to critical infrastructure like operations and staff it's really unclear how current performance levels can be maintained and how we can make good on our commitments to patients that on existing trials, let alone enhanced performance.

What I've been told -- and it's all antidotal which is why I'd really love to see facts -- is that the levels have been 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 to current trials. So that we really won't be able to finish current trials I'm being told on some of the entities with the operational statistical funding cuts, let alone do the new trials that we all hope are going to get done.

So, you know, it's very frustrating to hear that we can't get this information from the NCI. I don't now if it's accessible via FOIA but to be able to run around to the different groups. I think even if NCI could report at an aggregate level, you know, 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 that would be a good thing. And if there was a line, you know, to say that that tied to the funding that would be great.

Because it's not clear that if you cut the funding in the operation section for example that you can physically do the work required to do the accruals, it's different than cutting timeframes. So I'm hoping that you'll be able to respond in a detailed way post this call about the assumptions that are going in to make sure that we can meet the commitments that are being expressed for existing trials and new trials.

Jeff Abrams: Yes, okay well I'll take a crack at that and Dr. Doroshov may want to add to this. But, you know, 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, you know, it's been 21, 22, 23,000 a year on - in group trials. This number may have to go down, it sort of depends on what you call an enrollment. But we have calculated for this fiscal year that we could do 7 - about 71,000 interventional enrollments

and about a little over 2000 patients - 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 obviously 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 as I said we would earlier. So it may turn out that we have, you know, somewhere around 20,000 accruals this year.

But that, you know, our program is targeted to be a little but lower than it has in the past because we've added these new components to the system that I mentioned earlier. And we've built an approach to this, a prioritization approach with our disease-specific steering committees. Where every trial that's proposed by a network group gets rigorously evaluated and prioritized in term of it's impacts on - likely impact on changing the practice in that disease and really helping patients.

And so, you know, 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 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.

(Mike Kays): Dr. Abrams if I could do one follow-up here, you know, (Michael M) as a patient is - I'm being told that there are going to be problems meaning the commitments to enrollment and accrual to current trials and to opening the trials that have been prioritized by the steering committee. And I think that if

NCI is going to meet its commitments and deliver what it says it's going to deliver it needs to really look at this now because we can come back and fund this at the end of the year because by that time the breakage would have occurred. So I think that there's a real need for a perspective analytical view of this to identify where there could be breakage. And my gut says there's going to be breakage somewhere that we don't know about.

Thank (Mike) - go ahead.

Jim Doroshow: So (Mike) hi it's Jim Doroshow, I'd like to hear your voice, it's been a long time.

Just that I agree with you and what we are in the midst of doing because this has to be a partnership with (C) cooperative groups, we are in the midst of one-on-one meetings with each - 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 really what that, you know, research budget will support and what it won't support.

We've just begun that process but we're doing it now which is as about as fast after the notes awards came out as we possibly could. But to (prove you) we need to - without being from the group perspective what the resources can and cannot support it's really hard to know from a system-wide perspective, you know, how we will move forward.

(Mike Kays): Thank you.

Amy Bulman: Thanks (Mike), we will take the next question.

Operator: The next question comes from (Nancy Roach), your line is open.

(Nancy Roach): Thanks, sorry it took a sec to un-moot and thank you Jim and Jeff (in word) of pulling this together. I know this is obviously quite a busy time.

So here's my biggest question is that when we talked about this in 2011 and just for others on the call I'm on a clinical trials and translational research advisory committee CTAC where a lot of these things have been talked for. So I'm more - I have seen a lot of this stuff coming down the pike. But when we talked about it in 2011 there was talk of 175,000 - or no \$175 million budget and in it's infinite wisdom Congress made some decisions which I think make that challenging obviously because the budgets now \$151 million.

And so I guess my question is you can't really do 175 with 150 and so I - can you talk about how you're working with that? I mean I know that there's some regulations in terms of allowing flexibility, but are you looking at ways to be flexible? So for example would it be possible maybe to reduce the per case reimbursement from 4000 to 2000 and I know that's been hotly contentious over the years. But maybe in some cases it would be better to do that than to cut the operation budgets.

And I'm just wondering if you're looking at ways to minimize the impact of that kind of gap.

Jeff Abrams: Thanks (Nancy), we - that is the reason why we'd like to have these meeting over the month - the rest of this month of May with each of the groups and their financial officers to actually look for areas where we and they can be - show flexibility and creativity.

I would say that when we knew we weren't going to have the 175 million but rather we were going to have the 151, 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 may 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 would say I'm very hesitant to think about reducing the payments these sites that accrue a lot of patients because as you'll 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 did not reimburse the research better at the sites around the country and so that's a commitment we'd really like to keep.

However the other 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's care. So, you know, it is trade-offs, 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.

(Nancy Roach): So can I ask a follow-up?

Jim Doroshow: Sure.

(Nancy 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.

And I'm just wondering how do - as a community how do if we really want to take on shifting priorities at NCI to put more money into clinical research? A,

who makes those decisions and B, what do you suggest? Am I kind of putting you on the spot?

Jim Doroshow: (Nancy) I love you, okay. What else can I say, right? Let me just say this that, you know, we are - and it's not just the NCI, (NIH) is in probably it's most difficult position for - well easily 50 years in terms of funding levels and in terms of the money we have that and what's the purchasing power of that - those funds are.

So if anything your comment is actually - it's actually more difficult than most believe because even at the same level the (biomedical inflator) means that the same amount of money today is not the same as it would by five years ago. But, you know, both Dr. Abrams and I sit on the senior and leadership group that has to make decisions across the entire spectrum of things that the NCI supports. And I think that there's only one way to say this is that there's 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 meeting and people are losing their livelihood, losing their laboratory and because we're only able to fund grants on the 10th, 11th, 12, 13th percentile it's just it makes it extraordinarily difficult. When we can't fund translational research activities at levels that can bring things from the lab to the clinic in a way that those are expensive enterprises and those clearly have suffered, just every effort as (in many) to try to get the most with what we have.

And I do have to emphasize that I give credit to (Dr. Varmas) because truly of all of the large programs across the entire NCI and there are several that are big, I mean programs over \$100 million a year programs, right. It's really 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 will I will not cut. I think that shows he is committed to getting things to patients and taking advantage of all the wonderful and basic science that's going on.

(Nancy Roach): Okay, well you know what I think so (thank you) for what it's worth - thank you, I'll moot myself.

Amy Bulman: We'll take the next question.

Operator: Again if you would like to ask a question on the phone line today please press Star then 1 and record your first and last name, to withdraw your question please press Star 2. The next question comes from (Barbara LaStage), your line is open.

(Barbara LaStage): Thank you, good afternoon. I'd also like to thank you for arranging this call. I had submitted two questions beforehand but you've reassured me about one.

The other though and this may be a way to save some money is that I was watching this CTAC presentation last month and I was appalled to hear that there is a 25% failure to accrue rate in adult trials and trials that close because of this. And given the enormous amount of time and money that it takes to get a trial from the development of a concept within a group to open to accrual we're wasting millions of dollars.

And I applaud your streamlining of the system but since concepts start in the groups and then by the time they're actually presented to the steering committee it is - I have found it in my steering committee hard to ask

questions about what they have done to assure that they will be able to accrue the number of patients they need.

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

But these decisions - the answer to your question is that they're made jointly across the entire leadership of the NCI.

Jeff Abrams: Thanks (Barbara), this is Jeff again, you know you're right that we do not want to see trials that a lot of time and effort has been put into and patients have joined that - and then don't meet their enrollment goal.

So we have to do more and we recognize that. We spent a lot of time recently working on moving the file quickly from a concept - scientific concept to actually opening. Now we're going to shift our emphasis, now that we have timelines for that first stage to really working on better strategies on how to enroll. Looking for trials that may be excellent scientifically but may be hard to do and work on strategies to improve that enrollment.

Now fortunately in each of the network groups we have a lot of patient advocates, we have people who are explained in this field and we have now people trained at NCI in this field who are willing to work as a team to really come up with better strategies to improve the results of this trial. And I'm pleased to say one of the first ones you will see roll out with a much better enrollment package will be the new (lung matt) trail that is going to be done by SWOG.

I think you'll be impressed when you see the work that the professionals have put into making sure that enrollment on this trial is risk and that patients across the country are aware of this trial as well as their doctors. And we hope to, you know, use that type of effort to really improve our other trial efforts as well and really target trials where we think they'll be difficulties in enrollment and try to figure out strategies that will prevent this, you know, prevent the problem that you talked about.

(Barbara LaStage): Well and I'm very glad to hear that and I know when I was an advocate at Akron they were extremely welcoming of our finance about the ability for trials 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. But one of the things I would ask if you might look at the review sheets that we use when a concept comes into 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.

Jeff Abrams: Sure we - good suggestion. We do have something along those lines but we'll look into that.

(Barbara LaStage): Thank you.

Amy Bulman: Thanks so much (Barbara). Okay I think we're ready for the next question.

Operator: The next question comes from (Patty Spears), you're line is open.

(Patty Spears): Hi this is (Patty) I'm from the Alliance and I really wanted to reiterate I think what (Mike) said and what (Nancy) said were just really crucial.

I think the cuts that have been made to (Optsom Stats) are going to really impact what's going on now and what we can do in the future and things are happening now before you were talking because it's such a dramatic cut. And so I think that, you know, to say that we're going to maintain, you know, the trials that are ongoing is great to say but I'm not sure if that's going to be really reasonable without really no new trials going forward, so I think that that's just a real thing that's going on right now because of the cuts.

And then what (Nancy) said about the cut in funding, you know, you thought you were going to get an extra 25 million and you didn't yet you're still going through with the (laps). You're still going through with the big initiatives, the (Imadge Alkamaze), different things like that. So it doesn't seem like you've really done a lot to kind of mitigate that loss of 25 million. And so, you know, just kind of putting that in, in real 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 less trials available, so just keep that in mind. And then the accrual question was really (a propo) because I think in your operations is where that accrual happens, where your patient advocates are within that operational part of what's going on in the cooperative group - in the clinical trail network. And so by cutting that you're really cutting the things that we've, you know, gotten going some things that the alliance that are being cut because of the operation cuts.

Because when you cut operations you actually cut people and those people are the one's running (our accrual) taskforce and things like that. So I think that, you know, when you say things and, you know, all - it sounds good on paper, it sounds really good on papers, things had to change. And I think what has

changed has been really good, don't get me wrong. I mean central IRB and different things that have happened. The, you know, keeping an eye on accrual is something that we've long wanted and that's really good.

But, you know, these things that are just come down the pike or just really got everybody in a little tizzy because there are things happening right now and it is real.

Amy Bulman: Thanks (Patty).

Jeff Abrams: Yes I don't by any stretch of the imagination under the (minister) discomfort and difficulty in managing a tight budget.

We recognize that this budget is going to be required difficult decisions on part of the leadership in the groups that's why we want to have meeting with them, try to look for areas where we can be flexible and where they can be. The other thing that I'll mention that I'm hopeful will enable us to continue in the whole system to do good research is 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 they physician's can participate in any group's trial in the new system we may just 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. So we're willing to work with all the group chairs on these approaches so that the patients really 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.

(Patty Spears): And a follow-up on that, you know, just because a lot of things have changed with the different funding mechanisms and the last (bit) is a big part of it and there's not a lot transparent about that.

You know, who are the labs? You know, I know they've been notified and different announcements have come out, what is that funding used for within the lead academic institutions and (unintelligible).

Jeff Abrams: Yes, unfortunately since there's 30 of them those grants will - 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 hope pretty soon we will have all of them out and we will be happy to publish all the names of the labs to make that very available to everybody. As I said earlier they are some of the major cancer centers throughout the United States but we will make that more transparent to people. I realize it's sort of because of our grant process has been not as available as you would like and so we'll certainly move to do that.

(Patty Spears): Okay thank you.

Amy Bulman: Okay thanks (Patty). I will take another question, I believe we have time for probably about one more.

Operator: The next question comes from Rick Bangs, your line is open.

Rick Bangs: Hi this is - it was pretty clear coming into this meeting that we had a pretty formable task and so I'm interested in hearing what the engagement plan is with the advocates to move this forward from a policymaking perspective as well as a, you know, getting the facts on the table.

Amy Bulman: Thanks Rick, I think I can answer that a little bit but I'm going to - the first one is to Dr. Doroshov because I know that Dr. Doroshov and Dr. Abrams have a lot going on, on their end in terms of their communication with the group.

Jim Doroshov: So in addition to the individual meetings that we will be having it's actually - it's actually already started with the group chairs and their financial folks.

We will also have a meeting which (Dr. Varmas) will attend of all of the chairs with 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 I think that a lot, you know, a lot of - there's a lot of facts and figures that everyone has to agree to. And we need to know the impact of all of these various things on each of the various (groups).

As Dr. Abrams said I think it will be different from group to group and so that it won't be a simple single - singular response. It will probably require multiple responses to try to enhance what the overall network and ensure what the network can do based on the various circumstances that each of the groups is in.

Amy Bulman: Hi Rick and this is Amy from the Advocacy Office, thanks so much for bringing this up.

You know, 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 list serve 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 certainly, you know, heard that from you.

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

Rick Bangs: Yes so just this is to reiterate and one of my points is I think we need to hear what the policy engagement model is with the advocate.

What policies and decisions can we be a part of and I would respectfully point out that we are behind the eight ball on this and we must move with due haste. These are retroactive budget decisions that are being made here.

Amy Bulman: So in terms of policy decisions I'm not sure, you know, the institute has a policy of sharing information when it is publicly available as soon as we can. I don't know what policy decisions have been made retro- you know, that have been made retroactively. I know that advocates were involved in this (ETWG) and the IOM report. And there's advocate representation on CTAC and our other advisory boards and that's a lot of where our programs are discussed and that policies are proposed. So I'm not sure if I'm addressing your question but...

Rick Bangs: No, so I'm just going to give you one example and it's come up several times in this call, we are going from a large number of accruals - close to 30,000 or shortly under 20 down and so those - that has implications on strategy.

Those are policy decisions that the advocates should have a voice to the table. And I'm just using that as one example, so I think we need to hear specifically from the NCI what role you'd like to have the patient's advocate play as we are working through this recalibration of the budget, all right. I think we have -

we've earned a place to the table and I think we need to be specific about what place at the table we really have in this process.

Amy Bulman: Okay sure, well I think there's opportunities to engage through, you know, the NCTN work group strategy meetings.

You know, advocates are included in our - in the steering committee - so to do specific steering committees that review select Phase II and Phase III clinical trial concepts. You know, and then in terms of how you work with your individual group that is a part 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.

Jeff Abrams: Well one point I'd like to add because not everybody will know about this. Some of the people on the call actually participated in this, but over the last year and a half we've had multiple meetings of the NCTN working group and the CTAC subcommittee to advise NCI on how to prioritize.

Since we knew we would not have enough funding to do 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 on how we should form review bodies to help reach that. We're going to actually make a full presentation of this in July at the upcoming CTAC meeting and that will be made more broadly to the advocacy community.

But we already began a pilot that I'll just mention where we try to understand if we had many large trials proposed by the NCTN groups and we could not do them all, how would an advisory review or evaluation group prioritize amongst these different large trials? And, you know, we're - this is a challenging thing for us. We'd of course like to do all the trials but if we're

forced to choose for budgetary reasons we've been working hard to figure out the best evaluation process.

Amy Bulman: Thank you all. This is Amy again, we're running up against our time - I think we have time for one more question.

Operator: The next question comes from (Cindy), your line is open and it's our last questions.

(Cindy Gagan): Hi this is (Cindy Gagan) and I'm a long-term advocate and I really want to thank everybody, both who dialed into this call and for you Dr. Doroshow, Abrams and Stevens - Wortz McCaskill Stevens because this is a very difficult kind of conversation and we appreciate your starting it.

I think what - my question is more about what can we do as advocates that's constructive in this situation? Because I don't think there's any disagreement as the situation is unacceptable to all of us. And I guess I hope that if there were 25 million additional on the table we might not be having this conversation. And I don't - I know it's not up to the NCI to prescribe or direct what we do as advocates but how can - is there something we can do?

Because it's not just about priorities and things like that, there was an awful lot of planning that went into this and now it's kind of stalled and thwarted as a result of funds. So is there anything we can do that's constructive?

Jim Doroshow: I - so Number 1 I have to thank you for your participation. I think that for the last ten years we have really called upon the advocacy committee to help us as we plan these changes and the input has been invaluable.

And, you know, we are going to - I think 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 actually you couldn't even have conceived that we would possibly be able to do when we started the clinical trials (working group) because if you just think back even ten years we didn't have a single example of where a specific mutation in a solid tumor would direct therapy for that disease.

And it was in the spring of 2004 was the first evidence that that might be the case that came to bear. So I think that what we need - what you do these would be 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 that as Dr. Abrams said is a difficult thing but it doesn't mean that it's an impossible thing.

And that we really need to choose very carefully how to very best use that because these are a considerable amount - it's still a considerable amount of money. And I believe that there are unique efforts that where the 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, right. And that's happening in - on multiple levels and there are other examples.

And your help in really helping us to find what are the most important things that we can do as a cancer community - as a cancer research community are really at the heart of how we can move forward in a period where our resources are constrained.

Amy Bulman: Thanks Dr. Doroshov.

(Cindy Gagan): Thank you.

Amy Bulman: Okay so with that, you know, I think we'll wrap up our discussion today. I want to thank you all again for taking the time out of your afternoon to join us today.

There are many, many of you on the line, we very - and we very much appreciate your participation and your questions. They are clearly very thought out and they only help improve the process. So we look forward to continuing this dialog with you in the coming weeks as this - as both of these programs evolve and move on. Again my name is Amy Bulman and I'm with the Advocacy Office here at NCI and we look forward to working with you going forward.

If you have any questions you can send us an email or give us a call, we'd be happy to address them or find someone that can. Thanks so much.

Jim Doroshow: Thank you.

Jeff Abrams: Thank you.

Worta McCaskill Stevens: Thank you.

Operator: This concludes today's conference, you may disconnect at this time.

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