

## **Transcript of the NIH Stakeholder Teleconference on the NIH Workshop on Enrollment and Retention of Participants in NIH-Funded Clinical Trials**

Friday, May 16, 2014

### **Operator:**

Please stand by. Good day and welcome to the NIH stakeholders' teleconference. My name is Sarah and I am the moderator of today's teleconference.

I will review the plan and logistics for the teleconference and then turn the program over to the NIH host, Dr. Amy Patterson. After a brief introduction by Dr. Patterson we will move to stakeholder perspectives.

If you would like to provide comments I will let you know in a moment what you will need to do to be placed into the speakers' queue. The stakeholder perspectives portion of the teleconference will end at 4:25 pm Eastern.

We will hear from as many of you as the speaker - in the speakers' queue - as time allows. If you don't get a chance to speak today Dr. Patterson will explain in her closing remarks how to provide written comments.

This is not an interactive teleconference. Apart from the speaker everyone will be in a listen-only mode including the NIH host. At this point I would like to invite all of you who wish to be placed in the speakers' queue to please press star 1 now.

For those of you in the speakers' queue when it is your turn to speak I will announce your name and organization and ask you to begin your remarks. You will have two minutes to comment. After one minute and one-half I will break in to let you know that you have 30 seconds remaining.

After your two minutes are up we will move onto the next commenter. I will now turn things over to Dr. Patterson for introductory remarks.

### **Amy Patterson (NIH):**

Welcome everyone, my name is Amy Patterson I am the Associate Director for Science Policy at NIH. And we appreciate your interest in clinical trials and your efforts to enhance enrollment and retention of participants in NIH funded clinical trials.

I think many of you appreciate that the mission of our agency is to advance fundamental knowledge about the nature and behavior of living systems and then apply that knowledge to extend healthy lives and reduce the burdens of illness and disability.

In this regard clinical trials are an absolutely essential tool for discovery and improvement in the diagnosis, treatment and prevention of human diseases and conditions.

And patient participation is essential to the conduct of those trials and therefore absolutely a foundation for the work on discovering and improving diagnosis, treatment and prevention.

Also, as all of you appreciate, there are many challenges in participant enrollment and retention. At the same time there are many opportunities and we recognize that many different groups are trying different strategies in order to improve enrollment and retention.

We are going to be holding a workshop this summer in July, here in Bethesda, Maryland, and the purpose of the workshop is to explore ways to optimize participant enrollment and retention.

This workshop is going to be focused on identifying promising strategies, discussing the challenges as well as new avenues that together we could pursue in order to address some of the key issues.

Some of those key issues include how do we engage the most relevant populations in a particular clinical trial, how do we identify the study population in which particular interventions will be most effective and most safe, how do we promote individual and community participation in the development as well as the conduct of those trials and, importantly, how do we foster an environment in which investigators and research participants view one another as partners in enhancing public health?

So that leaves me to the purpose of today's call and today's call is all about hearing your perspectives on what concepts should be addressed in the July workshop.

And again the purpose of the July workshop is to not to rehash the history of trial enrollment and retention but rather to focus on what we can really do together to optimize it moving forward. The input that we'll receive on this call will help us in planning and organizing that workshop so that it really does advance the dialogue so that it explores promising, innovative and transformative strategies.

If we are unable to hear from all of you in the time we have allowed today we very much want to receive your comments via email and I will return to that at the close of today's call.

But the email address for providing written comment is posted on our website but we'll go over those details later today. If you're not able to stay on the call for the duration again, the email address for providing your written comments is on our website.

So with that let's begin, we're very eager to hear your input.

**Operator:**

And again to the audience that is star 1 to speak, we'll go first to Keith Fargo of Alzheimer's Association.

**Keith Fargo (Alzheimer's Associations):**

Hi everybody first let me say thank you for hosting this we appreciate that. And I won't take up very much time I just wanted to give four very quick recommendations on potential items for the workshop in July.

And two of them are very general and I think apply to most clinical studies and that is we may need to do a better job of educating the public about protections against employment and or insurance discrimination after they have participated in clinical trials because I think that can frighten some people away.

Number two, I think we need to explore ways that the NIH could encourage study sponsors to provide real feedback to participants after this study is done. I have the feeling that many times that is promised but often not followed up on and I think that would go a long way toward generating goodwill in the community and encouraging others to participate.

And my last two recommendations are really more specific to Alzheimer's and other dementias although somewhat general as well. One is can we design studies that have less burden.

And what I mean by that can they take fewer visits to complete and or could the visits be less burdensome in some way, maybe sometimes they could be done over the phone or they wouldn't necessarily have to last several hours the way they many times do now.

Can we increase education specifically for Alzheimer's studies that your study partner that you often need does not have to be a spouse because many people who have Alzheimer's do not have a spouse any longer.

Yet most of the people who have Alzheimer's who sign up for clinical trials do so with their spouse, thank you.

**Operator:**

We'll go next to Stephen Gruber with University of Southern California.

**Stephen Gruber (University of Southern California):**

Thank you I appreciate the opportunity to participate in this call and look forward to any valuable seminar coming up. I would just like to highlight that innovation really pivots on clinical trials and our academic partners including those of us here at the University of Southern California are really committed to providing the infrastructure for enrollment and retention of the maximal number of people on clinical trials.

And in particular we really want to serve our catchment area and make sure that we're identifying the most appropriate generalizable populations to enhance our ability for minority enrollment.

And here through mechanisms already funded by NIH including the CTSA and the USC Norris Comprehensive Cancer Center we are able to achieve that but I think we really should look at opportunities for public private partnerships and that that would be a valuable area for discussion.

In addition language specific patient navigators and culturally sensitive approaches to enhancing minority enrollment will certainly help us in achieving maximal enrollment accrual and retention onto clinical trials.

**Operator:**

We'll take our next question from Dana Dornsife from Lazarex Cancer Foundation.

**Dana Dornsife (Lazarex Cancer Foundation):**

Hi, Lazarex Cancer Foundation fills a resource gap for end stage cancer patients seeking life through clinical trial participation. We provide clinical trial navigation services and financial assistance to those who need it to cover the ancillary costs of participation and for a travel companion removing the primary barriers of knowledge, misperception and financial constraints and support network interruption.

We also work with the medically underserved to increase minority participation in trials. We have established a joint partnership called IMPACT, which stands for the Improved Patient Access to Clinical Trials between Drexel University and the Kimmel Cancer Center at Jefferson in Philadelphia, Massachusetts General Hospital and Ann Harbor in Boston and the University of Southern California and Norris Comprehensive Cancer Center in Southern California and the Lazarex Cancer Foundation.

The purpose of this partnership is to bring together the significant resources of the individual institutions and their affiliated medical centers, medical and social prowess and geographic and ethnic diversity.

This collaboration creates a powerhouse that is actively engaged daily in boots on the ground effort affecting significant and much needed change in the status quo of clinical trial, recruitment, retention and equitable access. And it's our intention to have a greater hands on focus with the medically underserved to encourage clinical trial participation and also to encourage physicians to offer clinical trials as a treatment option when standard of care has failed.

**Operator:**

Our next comment will come from Dr. Edith Mitchell, Kimmel Cancer Center at Jefferson.

**Edith Mitchell (Kimmell Cancer Center at Jefferson):**

Thank you very much, the Kimmel Cancer Center at Jefferson is an NCI designated cancer center, has a long history and a long track record of clinical trials participation and incorporating stakeholders into the process.

We have worked with physicians and other medical providers to define the needs of primary care physicians in terms of research and accrual to cancer clinical trials especially of underserved populations. We've also developed significant educational materials for the underserved population to increase accrual as well as keep patients into clinical trials.

One of the things that I think should be included in the workshop is the definition and the importance of primary care providers in the accrual and retention process for individuals into clinical trials and therefore an important part of it.

Another area is dissemination of information and that would include those media that have been successful in reaching populations. I thank you very much.

**Operator:**

Next we'll go to Salvatore Alesci, PHRMA, your line is open we aren't able to hear you please check your mute button.

**Salvatore Alesci (PHRMA):**

Thank you, sorry about that. I'm speaking for PHRMA (Trade) Association for the pharmaceutical industry, thank you again for organizing this call both our organization and our member company are very sensitive to the issue of increasing recruitment and retention and clinical trial.

I want to echo some of the comments already made by other organizations. We think in particular the issue of increasing diversity in clinical trials is a major issue one that we are currently addressing and prioritizing as in our association with our member company.

Two other perspectives that I think would be important to consider for the workshop is the importance of partnership between NIH industry academia, you know, to toggle these problems together. It seems not any single organization can really move the needle.

And the third aspect I want to bring up is I think we need to have a discussion about how to modernize clinical trials. Our current system is too siloed, there are no permanent infrastructures

being built in particular the issue of establishing clinical trial network both Internet based vitro and physical connecting the different players in the clinical trial system is probably one of the priorities that should be discussed in the context of this workshop.

Thank you for the opportunity to provide input.

**Operator:**

We'll go next to Greg Lennon, Snpedia.

**Greg Lennon (SNPedia):**

Yes hello I'm Greg Lennon representing Snpedia and ((inaudible)). And together we provide a free resource that's being used daily by many people to learn more about their own DNA.

We know that many people are receiving information about their own DNA and that of their loved ones from direct to consumer genomic testing services. And with that we see an opportunity for the clinical trial community.

Specifically our recommendation for the upcoming workshop is to discuss how to develop processes that will lead to invitations to participate in clinical trials and that those invitations can be included in the personal genome reports that people receive about themselves.

The invitations could be quite targeted: for example only to certain genotypes of relevance to certain clinical trials or to individuals who are predicted to be highly prone to diseases that are being studied in the clinical trials.

That's our recommendation. In other words, take DNA into account as trials are being designed and eligibility is set up, thanks.

**Operator:**

We'll hear next from Kimbery Hart of University of Rochester Medical Center.

**Kimberly Hart (University of Rochester Medical Center):**

Thank you. At the University of Rochester Medical Center we're coordinating an international clinical trial for corticosteroid treatment in Duchenne Muscular Dystrophy.

And a recruitment obstacle - subject recruitment obstacle - we frequently encountered is the actual activation of foreign centers for recruitment. So what I would like to see covered in the workshop is actually some guidance on how sites must register for the SAM database.

All sites including foreign sites need to register with the Systems Award Management database before we can pay them. And this has prevented us from recruiting subjects in these countries because the sites are finding the registration to be both confusing and cumbersome.

So I would very much like some guidance how we can assist these sites in making this a less painful process, thank you.

**Operator:**

We'll next go to Linda Wortman of Wortman Lung Cancer Foundation.

**Linda Wortman (Wortman Lung Cancer Foundation):**

Hi, thank you for the opportunity. I myself am a six year four month lung cancer survivor and I'm small cell. I was diagnosed at stage one by Mayo clinic when for two years my local doctors in Montana could not diagnose my symptoms.

First of all we need to reach out with greater public awareness with lung cancer by educating the public so they know that if lung cancer is caught in time - a life can be saved and you can have a great quality of life and lung cancer is not only a smoker's disease.

More research is needed, the only way to further our knowledge is through research, human nature is to want to help yourself, and to help others in the process, yet this idea of a study or a trial may be especially intimidating to lung cancer patients.

Public service information or what a trial is and how a study is performed might be helpful and of course education and awareness in the process for knowledge about even the more positive outcomes may prove to be very helpful.

Testimonies of people who participated in a trial or better those who benefited directly from a new treatment resulting from a trial may be helpful. There are usually incentives for participating in a trial and perhaps we need to enhance incentives for staying in a trial to improve retention. I myself just completed running a 5K race in all 50 states I am trying to teach others to dwell on the positives of what can be done with successful outcomes, thank you.

**Operator:**

Up next from Drexel University College of Medicine we'll go to Kenny Simansky.

**Kenny Simansky (Drexel University):**

Thank you I would like to highlight some of the comments made by our team members from the IMPACT team with Lazarex Cancer Foundation and Thomas Jefferson University and Southern California and also Mass General.

Together we are very interested, of course, in increasing enrollment of the underserved population of our society. At Drexel, we have a number of different models for community engagement, which I think needs to be an important part of the workshop.

Those different models are represented by the 11th Street Family Health Services Center of the University, which is a local neighborhood center that has comprehensive care for poor individuals from public housing units in that corridor and provides fully integrated community based care that's nurse-managed.

We also have a pediatric hospital St. Christopher's in a population that provides inter-professional management and physician management of a similar kind of catchment area.

We have an HIV clinic, which is one of the largest in the Northeast that has a similar population with a very specific disease focus and we have our local major hospital Hahnemann Hospital.

All of these in partnership with our friends at Jefferson University and other institutions in the region provide different kinds of models for educating these populations about opportunities for them for treatment outside standards of care and for furthering the development of therapeutics.

And we believe that community engagement needs to be an important aspect of this workshop, thank you.

**Operator:**

We'll go next to Steven Wakefield of HIV Vaccine Trials Network.

**Steven Wakefield (HIV Vaccine Trials Network):**

Thank you so much for the opportunity. We're looking forward to the outcomes of this workshop but really want to talk a little bit about our model, which is different for many of the people at NIH in that we work with prevention trials, large scale clinical trials to develop a product for people who may be at risk but are not yet affected by a particular ailment.

And what we found to be successful at our 36 locations on four continents is engaging stakeholders early and having operating principles that operate and work across all of our sites.

In all of our sites there's a posting of a participants bill of rights and responsibilities and we work not just with the potential trial participants but with the entire community to find common ground to build partnerships with institutions that will be in those communities long after our trials are there.

We have to understand the needs of the specific populations and then respect those needs and build trust with a commitment that we're going to conduct trials in a transparent manner.

For that, that means we have peer persons on all of our clinical trials decision making committees who work with us before, during, and after the design of a trial and throughout the implementation and to disseminate the results.

We have metrics we're evaluating our investigators relationship with the local community advisory board and we've built an evaluation plan that ensures that we can be responsive at every level of decision making. That requires not only the use of technology but actually building infrastructure for ongoing community engagement that's not just trial specific but that respects the communities need to know about risk and other science that may not be specific to any one given trial.

We look forward to a workshop that engages our stakeholders and we actually have papers that we've published to evaluate our processes.

**Operator:**

We'll go next to Janelle Allen, Cincinnati Children's Hospital Medical Center.

**Janelle Allen (Cincinnati Children's Hospital Medical Center):**

Hello, thank you for this opportunity to provide feedback and to have this phenomenal approach of taking our feedback to help create a workshop. I think there are a couple things overall just that would help clinical trials.

One would be to establish a platform for the collaboration with the NIH, the partnership that you have mentioned at the initial opening remarks of the call. We do have a great relationship with the NIH representative, (Linda Porter) and that's greatly helped us in development and maintenance of our trial.

It's great to know that she is at hand and a partner in our team. That I think would be a phenomenal approach of helping other teams actualize their grants and reach success in their recruitment and retention.

I think it also would be helpful to discuss other approaches that have helped trials that have been successful setting up a platform, a blog or whatnot that where we could share techniques and tactics as team across diseases and across institutes that may have been helpful whether that be cancer or headache or other areas because we have a lot that we can help one another with in our approach and again I thank you for this opportunity to reach out and to have a place to speak and to help create a workshop that will benefit all of us in our efforts.

**Operator:**

We'll hear next from Will Zrnchik of IPPF.

**Will Zrnchik (IPPF):**

I just want to say thank you for letting the organization participate in this event. And I want to say that consideration and concessions must be made for patients who are affected by rare diseases.

Due to the limited number of the patient population or their access to a trial site something must be done to increase the enrollment and retention. Now technology has advanced to the point where remote access participation must be encouraged.

This can be done through partnerships through local physicians or sites that are near the patients or even the use of personal devices such as tablets and Webcams that are coupled with in home medical specialists.

The outcomes of a trial should be more than advances in science but they should be accelerated and approved treatments for those affected by rare diseases.

The regulatory paralysis that exists in the pharmaceutical industry and the Federal Government must be eliminated. Companies are out there, products are available: we've heard discussions from some of them today.

The need for a standardized and simplified regulatory process with oversight that promotes patient enrollment and retention is a real one and that's one that can improve the lives of millions of Americans sooner rather than later, thank you.

**Operator:**

We'll hear next from Larry Chambers of Alzheimer's Society - excuse me of Canada.

**Larry Chambers (Alzheimer's Society of Canada):**

I have two points, one is that we were really interested in hearing about other disease associations that have developed guides to help each of their local branches and recruiting enrollment in clinical trials.

And we think that this is an organizational challenge for organizations like ours the Alzheimer's Society of Canada, we have 150 communities we work in with 70 different local societies.

And we want to enable them to do a really good job of increasing awareness, working with local researchers et cetera. So if there could be something on the program about how charities can be organized about recruitment that would be helpful.

Second the whole issue of the recent report from North Carolina about the lack of public knowledge about what a study is and what would be involved would be interesting as well.

People don't know the R work research and they also don't understand clinical trial participation, like for example, they'd have to sign a consent form and that you might be questioned or you might just have to fill in a questionnaire, you might not have to take a drug or you might have to take a medical device.

And someone already mentioned the need for expecting to have a report about the study. So more concrete things to help the public understand what's actually involved in participation in a study. Thank you.

**Operator:**

Up next we have Bruce Averbook Metro Health Medical Center.

**Bruce Averbook (Metro Health Medical Center):**

Hi there, I missed some of the early conversation I don't know if I was muted or something I'm not sure. But anyway my concern is that with the national clinical trial network LAPS grant system that it may be untenable.

There's not enough funds available to maintain research personnel, patient enrollment, to follow patients nor adequate funds for indirect costs to the academic and this - academic institutions to sustain oversight support.

If there is a move to utilize big pharma to supplement we will be compromising unbiased planning and conducting of protocols. In addition if we can't run large phase three programs in proof of concept how will we really assess our findings accurately.

We also have not been able to have enough funds for legacy follow up of patients before March 1, 2014. I think the system as it stands now will limit enrollment, limit creativity, create bias and decrease our ability to find cancer cures.

I think the NCI needs to find a way to better supplement the funds to the LAPS system and this would be one of the main challenges I think to this conference as we enter this new phase of research, that's all.

**Operator:**

Up next from Massachusetts General Hospital we'll go to Bruce Chabner.

**Bruce Chabner (Massachusetts General Hospital):**

Yes hi I've enjoyed all of these comments. I would just like to add that a major impediment to getting underserved patients on trial is the additional cost to them of participating.

It's additional visits, transportation in some cases accommodation and meals. And these funds are available to NCI or NIH subjects on NIH trials that come to Bethesda but nowhere else in the country are they paid for.

And I think NIH should consider evening the playing field for these other trials and either through public private partnerships or actually increasing the stipend for clinical research to include these costs.

They should do this in order to encourage participation of underserved patients.

**Operator:**

Moving next to Betsy Knight of KAI Research.

**Betsy Knight (Kai Research):**

Hi, this is Betsy Knight KAI Research, we are located in Rockville, Maryland and we're a small (sero). Many, many years ago Readers Digest published a booklet and I'm not sure what the title was but it was should I participate in a clinical research trial.

Unfortunately I don't have a copy anymore but it was a wonderful tool for us to hand to patients, potential subjects about what's involved in a clinical trial, it was very short.

I know NIH has something published on their Web site but it would be nice if NIH could do something that could be provided to researchers, primary care physicians, specialists that in very layman terms will explain what a trial is because many people think I'm a guinea pig and that's what you hear a lot from potential subjects, thank you.

**Operator:**

We'll hear now from Beatrice Bowie, research participant of NIH.

**Beatrice Bowie (Research Participant at NIH):**

My name is Beatrice Bowie I'm a patient at NIH and thank you so much for giving me a chance to participate. I'm very grateful for being at NIH because 10 years ago before I went to NIH I didn't have much to live.

But the doctors have helped a lot to the point that they actually have healed people with bone marrow transplant. And like the other lady indicated before when you go to NIH some people will think that you are a guinea pig.

So more education is needed to let people know that we are not guinea pigs and in fact it's a mutual beneficial relationship that we have with NIH. And the thing of it is we need more money for research and I think we are working on that.

I went to Congress recently there was an advocacy there for sickle cell disease of America so we saw a lot of our representatives who agreed to help us to renew the appropriation for the sickle cell with this money so that we can have more money for research and maybe one day they can find a cure for this disease, thank you so much for giving me a chance to participate.

**Operator:**

We'll go next to Rose Hallarn the Ohio State University.

**Rose Hallarn (The Ohio State University):**

Hi, my statements really are just more - much more general. I think in order for us to raise the awareness to the general public about the importance of participating we really need to have a mandate to encourage plain language to be used in every forum when we talk about it.

The general public doesn't like the words clinical trial they - trial is scary to them, they certainly don't like being called subjects, volunteers and participants is much preferred.

And the other thing that we have to be really careful about using is the word patient when we're trying to recruit patients. They may be patients in a certain office but when they are enrolled into a study and join the study then really participants are volunteers.

So as soon as we use that word patient when we're talking about them or to them there's confusion. So I just think part - I think it would be real important for part of the workshop to encourage the inclusion of plain language in everything, marketing, social media in one single message out there that it's important for everyone disease neutral message to participate in research, thanks.

**Operator:**

We'll go to Mark Quigg, University of Virginia.

**Mark Quigg (University Of Virginia):**

Hi, my name is Mark Quigg from the University of Virginia from the department of neurology and I have two comments. One is that regarding patient retention many times in study section a well-focused and simple proposal gets extra layers of burdensome additions as requested by study sections and turning this simple trial into something that sometimes patients have trouble remaining especially in longer trials.

So some sort of consideration of limits in how studies can become much more complicated than intended I would find useful. And the second comment is that certain procedure heavy trials, my experience has been in a recent epilepsy surgery trial that one of the barriers to recruitment was that many private neurologists were reluctant to forward their patients as a loss in revenue stream in this new day and age of financial awareness.

So in trying to build consortiums of small practices or smaller university practices facilitation to aid building of consortiums such as common IRBs, common contracting would be tremendously successful but as a model with (neuronet) and expanding that I think would be very helpful, thank you.

**Operator:**

Our next comment will come from Ann Melvin with the University of Washington.

**Ann Melvin (University of Washington):**

Yes thank you very much for this interesting conference. I just wanted to repeat actually what some people have previously said. I think some of the big issues that could be topics would be better information for the general public about clinical trial participation and the words that are used that and the implications for people.

That's something that at a national level could be done much more easily than is done at each local institution. The second is again what's also been said, which is that balance of the burden of participation with the need for very specific study design.

And I think like the previous speaker there's many situations where we've had a study design that's been relatively straightforward that has gotten layers of layers of additional criteria in order to make it a better study.

And so I think that's a topic of general interest in terms of new design ideas that would make actual study participation more feasible for participants. And then a correlator with that is more support for actual participant participation that's redundant.

But many times IRBs, because of the concern about coercion, will limit the amount of support that can be given to individuals to participate in trials where indeed that is a major barrier is the time off work, the complexity of trying to get places and those issues need to be looked at.

**Operator:**

We'll go to Thomas Kosten, Baylor College of Medicine.

**Thomas Kosten (Baylor College of Medicine):**

Hello, thank you. We've been involved primarily with conducting clinical trials in substance abusers, which is a very special population that we often have to pay them more to participate including that they are indigent we don't get any insurance coverage for their care.

And so I think that recruiting people into our trials has been a special challenge, and then of course retaining them in our studies is something of a challenge where treatment retention often depends upon these fairly modest financial and prize related incentives.

And I think one of the things important to discuss is how we use these contingency management procedures, particularly using prizes that are given, for a fishbowl technique for winning these prizes that is very effective with these populations in keeping them in the studies.

And then the final thing around treatment retention is that treatment retention doesn't make any difference if the people are not taking the medications. And so I think treatment adherence needs to be something that's considered within any of these discussions, thank you.

**Operator:**

And Sandra Reyna with University of Utah has our next comment.

**Sandra Reyna (University of Utah):**

Thanks for this time, I just want to say if there is any chance that in this coming workshop that it could be the theme of studies on pediatric populations and rare diseases or rare disorders affecting children would be a wonderful topic to include at the workshop.

We are challenged every time about recruiting patients not so much because we don't have the number of patients but mainly because there is not enough sites providing very specific trials for rare diseases in the pediatric population.

So if there is any way that that can be included in the workshop maybe even how to go about that and maybe what NIH is more able to do to provide more funding for other sites to be included.

I think that would benefit the population itself no matter what disease it is if it's considered rare it is rare that means very few patients are there to go around. But making only one or two sites only hold a trial that really is challenging for this community to be able to participate in trials.

I don't think retention is a problem for rare diseases because they are desperate to be able to have some options and I think retention is great too. So retention and recruitment wouldn't be a problem.

The problem I see with that possibility there is that there is not enough sites to provide this opportunity for clinical trials, thank you.

**Operator:**

And we thank you all for your comments. I will now turn back to Dr. Patterson for closing remarks.

**Amy Patterson (NIH):**

Thank you all for your participation we really appreciate all the ideas that we heard today, we've been listening very carefully. We're going to take into account all of what are really some excellent ideas for the development of the workshop agenda.

Again that meeting is going to be held in July 25 in Bethesda. We're going to be posting a lot of information about registration times and location on our website.

It's the same website where you found information about today's teleconference. Updates to the agenda and other relevant documents will be posted to the website in June so please stay tuned.

If you did not get a chance to present today or if you wish to amplify your comments and provide additional input somebody mentioned some papers that they had published that would be potentially relevant, we'd be happy to receive these.

Our email address is also on the Web site on the Web page for this call but I'll read it out to here and these are all in caps, O C as in cat R as in Robert, B as in boy and P as in potato dash O as in Oliver S as in Sam P as potato.

So O-C-R-B-P dash OSP at (@) O as in Oliver D as in David dot NIH.GOV and we would ask because we do want to move forward with developing the agenda and finalizing it, if you could possibly provide your comments by close of business on this coming Monday, May 19.

Thanks once again to each and every one of you for participating today and for your commitment to advancing research to improve diagnosis, treatment and prevention of disease and enhancing interest in our nation's population for participating in clinical trials.

And we hope to see many of you again at the workshop and with that I'll wish you all a wonderful weekend.

**END**