

**IECRN National Leadership Forum
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IECRN Overview**

Presenter:

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MR. DURAKO: Thank you very much, Jody, and welcome, everyone. It is great to see that we have such a large audience here this morning.

As Jody said, I am Steve Durako. I am a vice president at Westat and I am the director of our clinical trials area.

I have been involved in multi-center clinical research for the past 30 years, including some of the projects that were mentioned before, where networks were formed, and then they terminate after a single project.

But I have also been involved in the operation of clinical research networks for the past 20 years and I have to say I am a big, big fan of clinical research networks.

So it has been a great honor for me to be able to serve as the principal investigator for the IECRN project.

And I am delighted to be here today with so many people who are experts in the field of clinical research and I think this is going to be a golden opportunity for us to share ideas and to make recommendations to the NIH about how to

improve the use, the efficiency, and the effectiveness of the clinical research network infrastructure in this country, as well as around the world.

I know many of you and I appreciate you being here and I hope that I will be able to meet a lot more of you over the next two days.

I think that both Dr. Katz and Dr. Zerhouni, in their talks, should have motivated you to really address the issue of how clinical research networks can be made even better and can contribute even more to the translation of basic discoveries into the clinical setting and I hope that my speech will continue with that motivation and start giving you some information about our project.

So exactly why are we here? Basically, why has NIH chosen to sponsor a national leadership forum that deals with the issues of clinical research networks?

And even though Alan Morris would prefer not to hear this phrase, I think that, in a nutshell, it is because clinical research networks are one of the most effective vehicles for translating basic scientific discoveries from bench to bedside and I think a recognition of the questions that were raised to Dr. Zerhouni, when I am speaking about bedside, I am not speaking about the academic research center bedside, but I am

really speaking about implementation of clinical discoveries into practice-based medicine.

So that the patients who are in the real world, the majority who actually are seen by physicians in the community, are actually reaping the benefits of discoveries that have been made.

So what is so special about clinical research networks?

Well, in my mind, I think there are four key aspects of clinical research networks that make them very interesting and very important to the translation of basic science into clinical medicine.

The first point is that clinical research networks are already existing groups of investigators who have made some commitment to conduct collaborative multi-center research. I think this is very, very important, as Dr. Katz mentioned earlier, so that you are already in existence and you are not going to be starting from scratch every time.

The second is that clinical research networks are generally formed around a dedicated, multi-project, integrated agenda that is dealing with either a particular disease or a particular patient population.

So there is a continuity. There is a sense of

coherence and cohesiveness to a full agenda that is trying to address a particular problem.

The third important feature of clinical research networks is that they already have some sort of organizational structure in place that allows for rapid development and implementation of studies, and, again, this gets to the issue of not having to re-invent the wheel, starting from scratch.

And then, finally, clinical research networks, by their very nature of having multiple organizations involved, multiple clinical sites, generally have much greater access to patient populations than would research that is being conducted in a single site environment.

So I think we are all believers that clinical research networks are important and I think we all believe, from the talks we have heard this morning, that NIH recognizes that clinical research networks are important and NIH wants to use clinical research networks more and more effectively in promoting translation of basic science into clinical practice.

So what can we accomplish here today at this forum? I think we have four major goals for the next two days. The first is our team from the IECRN Project wants to communicate to you the findings that we have obtained from our study.

The second, and I think more importantly, is that we

actually want to discuss those findings and what they mean to you and to the clinical research enterprise.

So as you will see in this forum, we only have three hours of presentations about what we have done and then we have all the rest of the time available for you to participate and to tell us what you think and to come back with recommendations.

Third, we want to be able, as I said, to develop recommendations that we think will enhance the translation of research findings through the use of clinical research networks. We want to be able to present those to the NIH.

We, obviously, have some that we have developed from our project, but we are very interested in hearing your ideas and we hope to incorporate them into our final report to the NIH.

And, finally, we are here to try to engage the research community in implementing recommendations that will come out of this.

So I think that is not the end of the process here, these two days. After this is over, we want to continue with this process. We want to continue to engage you and we want to work with you and NIH on projects that will help us implement the recommendations.

So, first, to give you a little bit of background, so

you will understand what we are talking about today, I would like to go over, briefly, the major components of the IECRN Project.

There are basically four components to our data collection work. The first one we called the core survey and that was an effort to actually create an inventory, which I will talk about in a few minutes, of all of the clinical research networks that are in existence throughout the world.

The second component is what we called our quantitative or written component of the descriptive survey and the intent of that particular component was to actually develop a baseline of current practices in many different areas as to how clinical research networks carry out their work.

The third component was a follow-up piece of the descriptive survey, which was actually a qualitative telephone-based interviewing component, where we did semi-structured interviews with many representatives of the CRNs, to ask them about barriers and facilitators to them actually carrying out their work and accomplishing the missions that they had set for their clinical research networks.

Finally, the last component is something we called the best practices study. In the best practices study, we looked for networks that could demonstrate particular accomplishments

in achieving their goals and in achieving important accomplishments that NIH has recognized, and then, again, we conducted telephone interviews with these networks, looked at what they had accomplished, and tried to determine what approaches they had used to accomplish these and those were considered the best practices that are integrated in our presentations today.

So this is just a second attempt to try to help you understand what we did. This is a schematic that shows all the pieces and how they fit together.

As you will see at the top, the core survey is the one that I talked about that was our effort to identify all of the networks, and there are two purposes for the core survey.

One is to create the inventory that is available on our public Web site, which is seen on the lefthand side of this slide. The second function of the core survey was to give us a sampling frame from which we could select clinical research networks for our descriptive survey.

The descriptive survey, as I said, had two components. There was the written quantitative component that dealt with current practices within clinical research networks, and then there was the qualitative telephone interview component, which solicited opinions about barriers and facilitators to conducting

clinical research networks.

And then over on the right-hand side, a separate piece of the project was the best practices survey. And as you can see as you go down the slide, towards the bottom, the core and descriptive surveys have been summarized in what we call our core and descriptive reports, very aptly named, I think. We spent a lot of time working on that.

And those are available on our project Web site, which I will show you in a moment.

The best practices study interviews are summarized in a best practices report. That also is on our project Web site.

And, finally, all of those pieces are being brought together today in the National Leadership Forum, where we are actually integrating this information over all of these pieces into a number of short presentations that will lead you into the breakout sessions with food for thought and discussion.

So I guess one thing that we haven't actually done yet -- as I said, I am a great fan of clinical research networks. I think probably all of you are. But we really never said what we mean by a clinical research network.

What I am showing on this slide here is a definition that actually came out of the statement of work for our IECRN project. So this is a definition from the NIH, and I think

there are three important pieces of this definition.

First, a clinical research network is an organization of clinical field sites and investigators. It is a multi-organization entity. Second, a clinical research network is organized to conduct multiple research protocols, sometimes consecutively, sometimes concurrently, and I think this is where this differs from what Dr. Katz said about earlier clinical research networks, which were formed to do a single study.

And, finally, the clinical research network could be either a formal or informal structure, as long as it had demonstrated some collaborative accomplishments.

So with this definition, we set out to conduct the core survey and there were three primary objectives of the core survey.

The first was from the list of entities that we had identified, we wanted to confirm that each of them was actually a clinical research network, according to the definition that I showed on the previous slide.

Second, we wanted to collect some basic characteristics about each network that would help people understand how it was organized, what type of work it did, what diseases it studied and so forth, and that was going to be part of what we called the network profile, which we are including in

our public inventory.

And, third, we wanted to create the public Web-based resource by putting all of these profiles into an inventory that the public can access.

So what did we find when we set out to do the core survey?

Well, one thing that you might be surprised to hear, I was a little bit surprised myself, is there was actually no available list of clinical research networks anywhere.

It appeared that nobody had even attempted ever to create a list and, somewhat to my surprise, even some of the NIH institutes had some difficulty being able to tell us how many clinical research networks they sponsored, because the institutes are large, complex. They have many divisions, many branches, and there seemed to be, in some instances, none who actually knew exactly how many clinical research networks were being funded by an agency.

So when we submitted our proposal, we had a fair amount of experience with CRNs and we made an educated guess as to how many networks we thought we would eventually find, and we guessed about a 150, somewhere between a 150 and 200.

When we got questions back about our proposal, some of the reviewers said, "Well, that is way, way too low. There are

probably 2,000 clinical research networks out there."

You can appreciate that that made it a little bit difficult for us to budget and to figure out how much work we were actually going to do.

So we went back in and said, "Well, 2,000 might be a little bit high, but we will plan for maybe 300."

So after we were awarded the contract, we started snooping around every place we could. We used a lot of different methods to try to track down potential CRNs.

Part of it was personal knowledge. Part of it was contacting every government agency that did health research. Part of it was talking to many of you here in the room.

We, also, of course, surveyed all of the medical literature to look for any name that sounded like it might be a clinical research network, and, also, we went out and we Googled to look for names that sounded like clinical research networks.

And after doing that, we came up with more than 700 names that we thought could possibly be clinical research networks.

So with those names, we set out, we went out and tried to examine their publications, the Web sites of each of these groups to figure out whether they met the definition that I presented earlier.

We made some contacts by telephone, if we couldn't figure it out from their Web sites. And we eventually settled on 294 of these entities as probably being clinical research networks.

So then we set out to do the core survey. We contacted all 294 of these potential CRNs by sending them the core survey questionnaire and what we found, in the end, was that 32 of them actually were ineligible, according to our definition.

But it appears that 262 are actually clinical research networks. And one thing that I am very proud of, and I wanted to thank all of the IECRN team members who worked so hard at this, we got a positive response from 249 of the 262 networks that we contacted, which is a response rate of 95 percent, which, to me, I think, is amazing and I think that not only is it a credit to our team, but I think it indicates a recognition on the part of all of you, many of whom are in this database, that this is really an important project and that this inventory is really an important piece that is going to help us promote research within clinical research networks.

If there are any of you that are in the 13 that have not yet responded, you still have a chance. Please feel free to contact. We would love to have all 262 in our inventory.

So I am just going to whet your appetite a little bit with a couple of results from the core survey, but there is much more of this that is in the report that is on our Web site.

Of the first 244 responses that we were able to analyze, we found that CRNs are as old as 50 years, which is quite a long time, but some of them are as young as six months.

So these indicates that clinical research networks are still being formed and I think there will probably be more than come in the future, and we want to have them in our inventory. But the median age is about six years.

So a lot of the networks, almost half the networks are five years or less. So there are quite a few new networks.

Not surprisingly, the U.S. Federal Government is a major funder of clinical research networks. More than 60 percent have the U.S. Government as their primary funding source.

And the most frequent types of studies done by clinical research networks, again, not surprisingly, clinical trials are 39 percent.

One finding that I found interesting, there is also 28 percent who are doing some kind of observational research. So I think that this, again, addresses the point that not everything is a clinical trial and not all research has to be clinical

trials.

There is a lot to be done both in the epidemiology field, as well as in the observation of translation of findings into clinical practice.

One other finding that I thought was interesting about clinical research networks is where they are. This pie chart shows you just a quick snap of the location of clinical research networks.

As you can see, the majority of clinical research networks are U.S. based and I think that that is because the U.S. Federal Government is a primary sponsor of clinical research networks.

But that only accounts for 52 percent, just over half of the clinical research networks that we identified.

About a third of the networks actually now combine U.S. and international sites in their networks. And I think this is an interesting development that I have followed over the past ten years, especially in the areas of infectious diseases, HIV, tuberculosis, and others, but, also, in other chronic diseases, whether there has been an increased interest in dealing with these health problems, not just in the U.S. population, but in the world as a whole, and I think that that is a credit to NIH that they have supported that very

aggressively.

And, finally, there are actually some clinical research networks that we discovered that are totally outside the U.S., have only foreign components to them.

This is not a large number and I think, in part, it is due to the fact that most other governments do not provide the kind of support that the U.S. Government, and, particularly, NIH, does for clinical research, but nonetheless, there are some dedicated investigators out there who have established networks and are conducting research.

So those are a few findings. But what I want to emphasize is I think the inventory is actually the most important accomplishment from the core survey.

This inventory is Web-based. It is searchable. As Jody has mentioned, it has a profile of each of the clinical research networks on the Web site so that people can see who you are and what you are doing.

It is available to the public. It is intended to promote clinical research networks and to encourage people from the outside to actually contact you if they are thinking of doing research and perhaps that they can work with you in some way.

I think it is also important, we would like to

encourage all of you to use the inventory and contact each other.

One of the key missions in improving the use of clinical research networks is to create greater external interactivity among research networks and we think this is a valuable source for you to use to find out who is doing research like yours and how you might be able to collaborate with them.

So this is hard to see. This is a sample of a network profile that is on the inventory Web site. I didn't put this up here intentionally to promote the blood and marrow transplant clinical trials network, but I hope that the members of that network will appreciate just a little bit of free advertising.

Each of you who is in the inventory has one of these that is available for access by the public.

So this is the URL for the inventory. I have given a slightly longer screen name than Jody has. You actually don't need to write this down. You will be able to get it on the copy of the slides. It is actually on our little summary sheet that was out on the table before you came into the room.

There is also a demonstration of this that is accessible in the Randolph Room right across the way. That will be up there for the next two days and it is also where Kevin Peterson has his demonstration, for a little bit more free

advertising for all of those of us who are demonstrating any electronic systems today.

So just a few more slides on the inventory status. As I said, 249 networks have responded to us. We now have 239 profiles posted on the inventory.

There are a few networks who have asked us not to post their inventory and I think there can be some legitimate reasons for that and we certainly respect that. We are not posting anything without your approval.

But we certainly think that this is a great vehicle and if anyone wants to change their mind, we certainly welcome contact so that we can include you on the public inventory.

This inventory is intended to be a living, breathing vehicle. This is not going to stop today because we have had the forum.

Obviously, if this is going to be of use to you and to the public, we have to keep it up to date. We have to continue to add networks as we find them or as they are created.

So as part of this project, we are going to be doing an ongoing collection to try to identify additional clinical research networks.

We also have given you the ability to update your profile on this inventory at any time that you want. There is a

self-update feature that you can see when you go onto the inventory and if things change, such as your leadership or other things, you can send us a request to change your profile and we will do that.

We will also, just to make sure that people are looking at this, send out an annual query to everyone in the inventory to ask if the information that we currently have is up to date, and we would appreciate any changes back from you when we do that.

So is this inventory really any good and is it worthwhile?

This particular bar graph attempts to demonstrate how many hits we are getting on the inventory Web site and as you can see, we had a spike in one week in March, which I am not sure exactly why that happened, but on average, we are getting about 800 hits a week on this Web site and the average length of time seems to be about 12 minutes, which means whoever is getting out there is actually looking at something.

Now, many different people are using this Web site, but we have seen that there are lots and lots of individual users. It is not just Westat and NIH that are using the Web site.

And one thing I find very interesting is the largest

single user of the Web site is the Google search engine. So we are up there high on the list with Google and that means that people who don't know anything about this are actually finding us because we are a high profile site for clinical research.

So, again, I encourage you to use it and encourage you to be in it, if you are not in it.

In the rest of my slides, I am just going to go over, briefly, some of the methodology about the rest of the project and I will try to make it short and not too boring.

The descriptive survey, as I said, consisted of two pieces. There was the quantitative written component, where we tried to collect information on current practices.

We sampled networks for this component based on the core survey inventory and we sampled, roughly, 40 percent of the networks who were in the core survey sampling frame.

We sampled, over-sampled clinical trials networks and NIH-funded networks and we under-sampled international networks.

And the reason for this was that NIH and we felt that NIH would obtain the most information and most benefit from this project by looking at the clinical trials networks and NIH-funded networks in terms of what NIH would be able to do to promote the use of clinical research networks.

So we mailed surveys on practices, current practices,

to the sampled networks and we did this in seven practice domains that we felt were key to the operation of clinical research networks.

And here in living color are the seven practice domains. The first is management and governance. The second is financial practices. And those two, I am sure you realize, are fairly closely linked.

Then we had a set of very operational domains, network operations, recruitment and retention, and training and professional development.

And, finally, we had those that were related to computer systems and use of technology, the information technology domain, and the data management domain, which is also closely linked with information technology.

And I know that a number of you in here at least were participants in the descriptive survey and your network received all seven of these modules.

Some of the networks chose to have one respondent respond to all modules, which I thought was actually very sadistic, because it took somewhere in the neighborhood of five hours to answer all of these.

We attempted to find the best respondent for each of the modules, and the modules varied in length from about an hour

and 15 minutes to about a half-hour.

But we definitely, definitely appreciate all of the time that you spent responding to us. This is very important information and we know everyone is busy and this was a real commitment for you to complete these modules.

So then after we conducted the quantitative data collection, we followed this in the second half of the descriptive survey with a qualitative component, which were open-ended interviews conducted by telephone and these were focused on, as I said before, barriers and facilitators.

They were semi-structured interviews. We had expert interviews with experience in qualitative research and we actually did this for six of the modules. We did not include barriers and facilitators for financial practices.

I think we perhaps didn't want to hear all of the barriers that we might find there. But the barriers and facilitators in financial practices cross over most of the other domains. So we certainly found a lot of information related to financial practices.

Then the best practices study itself. This was done in a completely different way from the rest of the research.

What we felt we wanted was to find networks that could demonstrate that they had actually had some accomplishments.

So what we did was we developed a call for nominations. That call was very widely distributed through advertisements in journals, mailing to everyone who was in the core survey, and through a variety of other ways, including contacts with all of the agencies that sponsor clinical research networks.

This call was open from June to November last year. We decided that it was fair for networks to nominate themselves if they felt particularly strongly about accomplishments they had made, but others could also nominate networks for this best practices study.

And we focused on demonstrated achievement in eight categories and the next slide shows these eight categories.

These were actually also derived from the statement of work of our IECRN contract. I am not going to read them all.

I think a few that we found particularly interesting and fruitful for our research were the first two on the left side, internal interactivity within the network, external interactivity across the network, and, certainly, informatics, training, and expanding the research agenda.

But you are going to hear something in the following presentations that will basically touch on all of these key accomplishment areas.

And then the selection process, once we received the nominations, we created a selection and review committee. This committee consisted of a number of IECRN project team members who were content experts in the various areas, such as informatics, training and so forth.

It also included a number of our evaluation researchers and, finally, a substantial supplement from our outside expert advisory panel, who are people who are highly experienced in conducting clinical research networks.

And I have not had time to actually recognize the advisory panel by name. I don't have a slide here with that. But the advisory panel is listed on our project Web site. I encourage all of you to look at it.

I want to thank the advisory panel for all of the work they did in guiding us along and making sure that we were on target in what was important about studying clinical research networks.

So from the review process, we actually selected 29 networks for follow-up study and, as I said, these were based on evidence of accomplishments in one or more of the eight accomplishment areas that I showed on my previous slide.

We were willing to take networks that had only demonstrated accomplishment in one area, if that was our

particular focus, because we wanted to see what their practices were, but we also took networks that demonstrated accomplishments in multiple areas.

So this was followed by in-depth telephone interviews by qualitative interviewers, along with content experts in the particular domains.

We tried to identify the person who was the best respondent for the network. Then from those interviews, we tried to find the practices that contributed to their accomplishments.

And I think that is actually my last slide. There is a lot, lot more information. So if you want more information, again, you can visit our Web site and look at the reports part, where all the reports I showed on this schematic are up there.

And before I wrap up, I want to say thank you to all of the team members of the IECRN project. I would certainly like to thank Nancy Dianis, our project director, who will be up here later this morning giving you some of the results.

I would like to give a special thanks to the leaders of our evaluation and qualitative research team, Susan Berkowitz, from Westat, and Darcy Strouse, from Aspen Systems, and to the hundreds of others who have contributed.

I won't name you all, but thank you very much.

I have a little bit of time for questions before we move into the break. So the floor is open.

[Applause.]

DR. BRUBAKER: My name is Linda Brubaker. I am Assistant Dean of Clinical and Translational Research at Loyola in Chicago.

And I find this really fascinating and I am hoping that in your future plans or future contracts, you will be able to begin to work to integrate this registry with the registration of clinical trials that are open for enrollment.

Is that going to be a possibility? So that people who go to update their network or their trials don't have to do simultaneous or --

MR. DURAKO: Yes. That is a very interesting and important question. In fact, we had some discussion about that during the course of the project.

Jody and we were working together to see if we could directly link from our inventory into Clinicaltrials.gov, so that you could actually see the trials that a network is doing. It's complicated.

The names of the networks, the way to link to them is not the same. I think Jody wants to say something a little bit more about what we actually did, what we found, but I think it's

certainly a goal for the future.

Yes, Jody.

DR. SACHS: Thank you. We are trying to make that process streamlined so that you can actually link and look at what networks do what trials and I think that is what is essential and needed.

Thank you.

MR. DURAKO: I think we actually now do let you jump into Clinicaltrials.gov, but it doesn't give you that network specifically. It gives you a list of studies that seem to be related to the disease that you were interested in.

So it is not perfect now. We have to work with the NLM folks on that.

Carol?

DR. HAMILTON: Carol Hamilton, Duke University and Duke Clinical Research Institute.

I had a couple of questions and comments. One, it was very interesting, the graph that showed how many of the networks were U.S.-based versus elsewhere.

So one question was did you -- I assume you only searched in English. So there could be sites that are totally listed in other languages.

Would that be true?

MR. DURAKO: It is fair to say we only searched in English, although we certainly found networks, like the Netherlands-Australia HIV Network.

Yes. We did not have that capability and I think we felt that in terms of, I guess, the U.S. orientation, particularly NIH orientation that those networks probably would be a little bit difficult for us to be able to work with at this point.

DR. HAMILTON: And probably the major ones would be on a site that is listed in English.

MR. DURAKO: Yes.

DR. HAMILTON: But I think that will be really interesting to look at over time, because as you know, I mean, I know, for instance, Singapore has made really a government commitment to developing an infrastructure so that they can carry on clinical research in the future.

So it will just be interesting to see how that evolves over time.

Which leads me then to the next question, which is did you have an opportunity to talk to any of the pharmaceutical industries, because they also fund and coordinate various networks and I didn't know if they would show up in your survey.

MR. DURAKO: We certainly tried. If there were any,

they would show up. What we found, much to our amazement, is there seemed to be no actual clinical research network, according to our definition, that is totally sponsored by the pharmaceutical industry.

And, again, I think, as Dr. Katz says, they are usually one-study groups of clinical sites. Pharmaceutical industries are not necessarily in the business of just continuously funding a general research agenda. They are targeted to approval of particular products.

So we did not find any. I was very, very surprised by that.

DR. SACHS: And I just wanted to make one clarification that CROs were not included in this inventory.

MR. DURAKO: Yes. I think with that clarification, CROs conduct and manage projects, but they aren't, in our view, actually networks themselves.

Otherwise, Westat and many other organizations would be in this inventory, and that is not what it is for.

DR. GILBERT: Gregg Gilbert, University of Alabama at Birmingham.

Of the 264 or so clinical research networks that you inventoried, what percent of those would also classify themselves as practice-based research networks, do you think?

MR. DURAKO: You know, that is a number I don't have, off the top of my head. We could find that. I think there are a fair number of them.

There are probably at least 60 or so. In fact, Kevin Peterson, you now the federation. How many? You said yesterday 50-some in the Federation of Practice-Based Research Networks.

DR. PETERSON: (OFF-MIKE)

MR. DURAKO: So Kevin says there are probably 80 to 90 practice-based research networks. I hope we got them all. We certainly tried.

DR. CAMARGO: This is Carlos Camargo, from Mass. General. Thank you for expanding the bedside across the land.

MR. DURAKO: Yes. I thought that was very important. It is not just to the tertiary care center.

DR. CAMARGO: I had a question for you, which is you mentioned that this initiative will be going into the future, with plans of integrating with other databases.

Just briefly, what kinds of outcomes will you be tracking to measure the success of the enterprise?

MR. DURAKO: I think we haven't totally defined that yet. We are going to have a session after this with NIH to see what kinds of recommendations come out of here.

And I would say that some outcomes that I would like

to try to measure are -- you know, how many networks actually start working together with each other, this is something we will, obviously, have to collect additional data on to know that.

I guess I would like to see whether we start seeing some individual investigators who are applying for research funding actually being directed toward clinical research networks to support and facilitate their work and I think this is something that, obviously, NIH needs to consider in terms of how it makes awards.

I would like, in the information technology area, to see whether, in fact, we start making improvements in some of the things that you will hear about later, about use of electronic systems for data transfer.

One outcome I am particularly interested in, and I can tell there are lots of practice-based researchers here, I would like to see whether the support for practice-based research networks actually increases in some fundamental and measurable way.

One of the things that we found in our research, one of the difficulties we had, actually, in surveying practice-based research networks is many of them don't have an infrastructure.

So we contacted some of them and they said, "Well, are not really active now. We are funded study-by-study. We are dormant. We don't have funding. We don't have anybody who can answer your questions."

So I think that if we are really going to take advantage of the community, and this is something that Dr. Zerhouni talked about, as well, you have to get out into the community where the real patient are.

You have to provide some mechanisms of support to do that. So that is something that is a very strong recommendation on my part.

It is not all basic science. It is like what do you get out into the real practice community and how do you make it easier for investigators or clinicians to practice as investigators.

Another slight corollary to that is I would like to see whether any changes are made in the academic promotion process in terms of what is important.

I will presenting that on my next slide as to what it takes to participate in multi-center collaborative clinical research.

DR. SACHS: In order to keep moving, we have time for one more question and then we are going to take a break.

Thank you.

MR. DURAKO: Steve? Two more questions, one at this end, one at these end.

DR. SACHS: One more question over here and then we are going to take a break.

Thank you.

DR. MOLD: I am Jim Mold, from the University of Oklahoma, with the Oklahoma Physicians Resource/Research Network.

I now belong to three registries that I am aware of: the Federation of Practice-Based Research Networks Registry, the AHRQ, the Agency for Healthcare Research and Quality's resource center registry, and now your registry.

The last two of those required a fairly lengthy survey and more survey is coming. So I would argue that this is the first one, this is not the first one, but that we need to sort of coordinate our efforts, at least in the Federal Government.

I realize that there are going to be some private sector things that maybe can't be coordinated.

My question is that with -- I am involved in one of the breakout groups and it struck me, as I read the data, that there is a tremendous non-homogeneity among the networks that you surveyed, I mean, anywhere from -- I'm not sure whether the

dental networks were involved in the surveys or not, but anywhere from ICU to nursing home to hospice to primary care practice.

How did you deal with that non-homogeneity with regard to analysis of the data or even coming up with the right survey questions?

MR. DURAKO: Thank you, Jim. Those are important issues.

First, I would say that we did hear as we were doing this survey that AHRQ had beat us to the punch for the practice-based research networks and we appreciate your tolerance for participating.

And I think that points, again, to trying to link these databases so that we don't become 20 of them.

On the issue of homogeneity, we certainly were interested in homogeneity. We were trying to find everything that was a clinical research network and we defined clinical very broadly as conducting any kind of research in humans, any kind of health-related research in humans.

So certainly dental is in there, hospice is in there, epidemiology studies are in there, behavioral research is in there, and that did make it difficult for us to ask the questions broadly enough that everybody could answer them.

We did this partly by spending a lot of time on survey design, with a variety of folks from different networks. We did some pilots with a group of networks to see if the questions made sense. We used our expert advisory panel, which covered a spectrum of research types, to see if the questions made sense.

And then we sent them out and sometimes they didn't make sense to certain people and they simply couldn't answer them because it didn't apply, but we tried to do the best we could.

DR. SACHS: Thank you, but we are running out of time. So what we would like to do is take a short break, 15 minutes, come back around --