

**IECRN National Leadership Forum**  
**May 31, 2006**  
**Welcome**

**Presenter:**

**Stephen Katz, MD, PhD**

Director, NIAMS

DR. KATZ: Thanks very much. It is a pleasure to be here. And I think the reason I have the honor of welcoming and doing some introductions this morning -- can you hear me back there?

The reason I have the honor of doing some introducing is because I think I was there at the inception of this contract, that we are seeing some of the conclusions that have been drawn, and this component of the roadmap was one that there was pretty much uniformity that was needed.

So let me, for those of you who don't know about the roadmap and how this effort came about, through NIH funding, it came about because we had many meetings with the extramural community. Some of you who I see in the audience were a part of those meetings. And we talked about what are some of the roadblocks in terms of science moving forward that the NIH and probably no one else would support.

And out of that came three different, although often interdigitating, activities. One was new pathways to discovery. Another was interdisciplinary research. The third was re-

engineering the clinical research enterprise.

What we heard, and these were all meetings that Dr. Zerhouni chaired, with other of the institute directors, what we heard with regard to re-engineering the clinical research enterprise was what were some of the roadblocks.

One of the major roadblocks was that there was really no real home for clinical research, which, as you will hear from Dr. Zerhouni, is being addressed now through the evolution of the roadmap.

Other areas were areas of being able to assess quality of life issues, which we have addressed; the development of more clinical research scientists, which we have addressed.

But one recurring theme that we heard was that the development of clinical research networks was a real difficult procedure. That is, they would be developed for a project and then they would fold.

And I am sure many of you all have been a part of some of those types of research networks. Many of the institute directors and many of the people from the community embrace the concept of trying to develop a system where we don't have to build up and break down a network every time we want to do a study.

The example that I gave early on was in the pediatric

arena. So for pediatric rheumatic disease, we would, whenever the institute had a need to do a study or the community came in with a very good study, a network was developed; after the study was done, the network was folded.

Well, there must be more efficient ways to do that and I think that is what we are all about for these next two days, is to figure out how best to do that without the enormous expense of building up these networks and then not utilize them or utilizing them for unique types of questions, rather than to try to build a home and a region for networks where there can be continuity of studies and better utilization of all of the elements that are required for these types of studies.

Early on, Claude Lenfant and I co-chaired this part of the roadmap activity and then Steve Straus, who is the Director of the National Center for Complementary and Alternative Medicine, co-chaired it with me.

A critical person in the inception of this particular activity that we are going to be talking about these next two days was led and spearheaded by Larry Friedman, who was at NIH for quite some time, a renowned clinical investigator, and, when he left, Jim Kiley, from the National Heart, Lung and Blood Institute, took over, and now Jody Sachs. We are grateful to Jody for carrying the banner not only for last year's meeting,

but also for this year's meeting, and for publicizing it to a point where lots of people are not only here, but, also, as I understand it, watching this on a Web cast.

So I think that is an accolade. Thank you very much.

From Westat, we have Nancy Dianis and her assistant Smita Amin and all of her staff, who have been very, very helpful in putting this--critical in putting this activity together.

I must say that the person who is really in charge from the NIH at this point is the acting Director of the National Center for Research Resources, Barbara Alving, where this whole activity is in her aegis at this particular point.

I have had an opportunity to look at the executive summary and at the report that has been provided; not the total report, because it has not been out yet, but most of the report that came from Westat.

For those of you who have seen it, you will know there are no real surprises there. It is, what you would say, "Hey that is what we would have expected." But in its totality, from my standpoint, it does provide a blueprint for putting together networks that are going to not pop up and die down, but that can persist and answer questions that cut across the board in the clinical research arena, not only in terms of clinical trials,

but other types of clinical research that is so critical to the health of our nation.

So I think that this provides a blueprint. I look forward to hearing the deliberations of this meeting. I know there are breakout sessions.

We are anxious to hear what you all think about the various subdivisions that Westat has put this perspective in. I know that they actually sent out inquiries to something like 700 different groups, and I know that this evening there will be some recognition of those networks that have the semblance of best practices, and we look forward to making those presentations this evening.

So this is a wonderful start. It is the culmination of a lot of things that have been going on at NIH for a number of years.

And I do think that those people who came to those meetings and talked about the roadblocks in terms of networks would be gratified by seeing this particular report and by hearing some of the deliberations and presentations that are going on in these next days.

So I have told you a little bit about the history, and, now, Dr. Elias Zerhouni, who has been the Director of the NIH for almost exactly four years, perhaps four years and a few days, who, actually, when he came to NIH, said that we need to address some of the roadblocks that we haven't addressed collectively, and I think it is to his credit that all of this came about.

And without further ado, Dr. Zerhouni is going to give us an NIH roadmap update.