The Clinical and Translational Science Awards (CTSAs) of the National Institutes of Health (NIH) were created to provide the resources that the clinical researcher needs to proceed with research rapidly, safely, and in a strong academic environment. The CTSAs offer different opportunities that meet the needs for training people to do clinical research and to provide those researchers with an environment in which they can research.

THE HISTORY OF THE CTSA

The NIH used to provide clinical research infrastructure awards that were all extremely narrowly focused. For example, awards were for education, or training and research, funding to support nurses, or funding for clinic space. The NIH did not combine these awards to create a coherent entity: an organization that could efficiently interact and provide the services that different investigators needed. Also, outreach to industry (which is responsible for much of the innovation and the production of new drug trials) and to the community was missing. Infrastructure support before the CTSAs was fragmented: without creating the whole from the sum of the parts. The NIH had good animal resources, outstanding imaging, and strong clinical components. We needed to put these resources together to create a new “home.”

Also, because we considered what clinical researchers would need, we identified biostatistics, informatics, nursing, clinic space, and ethical input into the creation of consent forms, among other support. We realized that if we could provide this support before the researchers designed their clinical trials, their studies would proceed faster and more efficiently. We also realized that if we were going to provide an environment in which people would be mentored, we needed a training environment with the potential to award a higher degree.

We therefore linked a series of programs to create the CTSA program in an academic network that would include a university component that was capable of awarding higher degrees. The CTSA program has now been active for approximately 2½ years. Clinical and Translational Science Awards are made for 5 years, so now is a reasonable time to ask, “How are we doing? Where are we going?” To succeed and reach across the nation, we anticipated that we would need 60 sites (Fig. 1), and we had 38 sites until this year when we welcomed The University of Cincinnati as the first award in 2009. We will announce other awards later this year. We currently have 39 CTSAs, and we are striving to encourage these awardees to work as a consortium for mutual benefit.

THE COLLABORATIONS OF CTSAS

To explain how these sites work and what their links to health care organizations, industry, and other agencies mean, I would like to use the CTSA at Emory University as an example. The CTSA at Emory sent us a nice slide (Fig. 2) that illustrates how the investigators put together 2 universities—Morehouse and Emory—to jointly operate their CTSAs. Their collaboration builds out the paradigm of working efficiently with available local resources. The CTSA then built ties with the Primate Center at Yerkes to advance informatics at Georgia Tech and with biotech enterprises through GeorgiaBio, the Research Alliance. The CTSA is also reaching out to the Atlanta Veterans Affairs (VA), which will enable researchers at the Atlanta VA to make use of the CTSA resources, and likewise, the CTSA investigators can access patients through the VA. The investigators wanted to be able to do pediatrics research, so they also partnered with the Children’s Hospital. Finally, they are partnering with another government-funded organization, the Centers for Disease Control and Prevention.

By affiliating all these organizations through a CTSA application, the Emory CTSA rose to a level at which the reviewers were delighted to say, “Yes, you know, this is an outstanding organization. They should be funded.” The Emory example is not unique; I could share similar successes at Yale University and Harvard University and in Philadelphia and Pittsburgh and many of the other places that we have funded.

The size of each individual CTSA budget, and so the resources available to investigators, vary (Fig. 3). The larger institutions came in first, so the average size of the awards in the first year was just more than $11.5 million. By 2008, our average award was approximately $7 million. Perhaps the smaller institutions delayed their applications so they could put together the affiliations to create an impressive home. The sort of infrastructure that these awardees try to provide is diverse (Fig. 4), and they are still evolving as they should be. Most important was the community engagement that allows these CTSAs opportunities for clinical outreach so they can conduct community-based participatory research for comparative effectiveness research. This engagement with the community and the opportunities for translational technologies that will secure community adoption is new to the NIH. Every CTSA must have an evaluation component so the investigators can self-evaluate. Each CTSA also must have an external advisory board that provides advice on which the investigators can depend.

THE ACCOMPLISHMENTS OF CTSAS

The CTSAs have succeeded at training the multiple members of a clinical research team. As we look at the range of awardees (Fig. 5), we can see that they have, among their
scholars, their trainees, statisticians, informaticists, dentists, and young physicians in medicine, pediatrics, obstetrics and gynecology, and the entire range of the clinical spectrum.

Investigators are working on informatics support, which is valuable and aligns well with the current administration’s emphasis on health care informatics and community outreach. Investigators also need to mentor researchers to independence so that collaborators trained through the CTSA have a better chance of obtaining R01 grants. They are also working to rationalize their support for research cores and for infrastructure support.
investigators are also going out into the community to say, “How do we effectively explain to people why they should participate in a clinical research study?” which is a key issue. If we want to carry clinical research forward faster in the United States, we need to be able to enroll patients faster, which requires that we educate the public as to why they want clinical research to take place and so they do not consider research only as a risky activity.

Communication is obviously very important for CTSAs. To some extent, we are seeing regional groups develop, based on educational experiences, such as the states in the western United States, which have united. The midwestern states are also working together, and they decided to organize outreach into their neighboring states. Awardees in the New England states have also been efficient in getting together. Other areas do not as yet seem to be regional organizations, but they will self-assemble when they are ready.

The NIH needs to ensure that CTSAs are meeting our goals. One way to measure this is to ask, “Are CTSAs serving the needs of the NIH investigators?” We look at the CTSAs to ensure that they are providing support for people who get grants from the NIH to conduct basic and clinical studies and who need our infrastructure. Most of the studies active at CTSAs are supported by National Institute of Diabetes and Digestive and Kidney Diseases, whose grants include studies of diabetes, kidney, liver, endocrinology, and other areas. Numerically, these are followed closely by heart, lung, and blood and then followed by cancer, neuroscience, mental health, and many others.

THE REACH OF THE CTSAS

We are achieving the diversity that investigators need and that the NIH wants and, considering the 39 CTSAs that we have (Fig. 1), one of our greatest concerns is “How can we adequately reach the researchers in the community who could make use of the support that we could provide?” We address this question at different levels.

First, we need to look beyond the geographic level and say, “Within a city where there is a CTSA, are the CTSA resources adequately available to people in the different schools, for example, bioengineering programs, the school of nursing, and the school of pharmacy?” We need to ensure that CTSA investigators and administrators are creating adequate links within the components of the CTSA and within the awardee institution. We hope that regional groupings will succeed in offering CTSA resources to researchers, NIH-funded researchers in particular, as well as other institutions in their areas that do not have a CTSA. We are also prioritizing how to encourage all CTSAs to function as a consortium and to work together for the greater good. While investigators typically compete to obtain NIH grants, once a CTSA has been established, the investigators are then expected to work together.

FIGURE 3. Resources available to investigators vary.

FIGURE 4. Diverse activities that CTSA consortiums conduct.
The National Center for Research Resources also runs the Centers of Biomedical Research Excellence (COBRE) and Institutional Development Award Networks of Biomedical Research Excellence (INBRE) programs. These programs provide NIH funding to states that have a lower average level of NIH funding. These IDeA states are now an active area for outreach by the CTSAs. Examples include the Mayo Clinic and the University of Washington, whose investigators are actively reaching out to the states with which they are aligned to share resources.

This overview presents the range of activities that CTSAs provide. Winning a CTSA is a highly competitive process, and the awardees help us to create an environment in which we can deploy our clinical research resources in the most cost-effective way.

FIGURE 5. Institutions and consortiums that compose the CTSA at present.