

CTSA Consortium Oversight Committee Meeting October 3, 2007

National Institutes of Health, Building 31, C wing, Room 10

CTSA Consortium Oversight Steering Committee Members Present:

- **CTSA PIs:** L. Berglund, Co-chair (UC, Davis); R. Califf, Co-chair (Duke Univ.); F. Arnett (Univ. of Texas HSC); G. Bernard (Vanderbilt); B. Collier (Rockefeller Univ.); D. Clauw (Univ. of Michigan); P. Davis (CWRU); M. Drezner (Univ. of Wisconsin); M. Disis (Univ. of Washington); D. Rader (for G. FitzGerald, Univ. of Pennsylvania); D. Ford (Johns Hopkins); T. Pearson (for D. Guzik, Univ. of Rochester); H. Ginsberg (Columbia Univ.); G. Hunninghake (Univ. of Iowa); M. McCune (UCSF); M. Packer (UT Southwestern); J. Imperato-McGinley (Weill Cornell); E. Orwoll (OHSU); K. Polonsky (Washington Univ.); R. Rizza (Mayo Clinic); S. Reis (Univ. of Pittsburgh); R. Sherwin (Yale Univ.); J. Solway (Univ. of Chicago); D. Stephens (Emory Univ.)
- **NIH staff:** B. Alving (Director, NCCR); A. Hayward (NCCR), CTSA Program Director; L. Ramm (Deputy Director, NCCR); M. Ames (NICHD); J. Atkinson (NIDCR); J. Bao (NIMH); T. Beck, (NCCR); E. Collier, (NCCR); M. Corn, (NLM); M. Dufour (NCCR/Madrillon); G. Farber, (NCCR); R. Filart, (NCCR); F. Greider (NCCR); E. Hadley, (NIA); K. Huss (NINR); K. Hardwick (NIDCR); A. Injerra (NCCR/BoozAllen); K. Kidd, (NCCR); A. Krensky (NIH/OPASI); S. Lane (NCCR); J. Marler, (NINDS); M. Marron (NCCR); W. Martin, (NIEHS); D. McCloskey, (NCCR); S. McClure (NCCR); S. McNairy (NCCR); M. Michel, (NIDA); L. Mulligan, (NCCR); J. Musgrave (NCCR); P. Newman (NCCR); I. O Abrams, (NCCR); D. Rosenblum, (NCCR); J. Sachs, (NCCR); A. Sawczuk, (NCCR); M. Sayre (NCCR); M. Scheideler, (NINDS); D. Sheeley, (NCCR); C. Shreffler, (NIEHS); S. Shurin (NCCR); B. Smothers, (NINR); B. Tai, (NIDA); B. Talbot, (NCCR); M. Tingle (NCCR); M. Walton (FDA); L. Weiss, (NCI); D. West, (NCCR);
- **Other CTSA participants:** S. Autry (UCSF); M. Blosinsky; K. Dellarocco (Yale U.); D. DeMets (U.Wisconsin); B. Evanoff (U.Washington); M. Gillis (UC Davis); M. Goode (UTHSC, Houston); T. Johnson (Yale); D. Mathias (U.Pittsburgh); E. Ofili (Moorehouse); S. Olson (Mayo); R. Rudit (CWRU); H. Schwartz (U.Washington); C. Sorkness (U.Wisconsin); L. Yasko (U. Pittsburgh)

Welcome and Introductions

Dr. Barbara Alving, Director, NCCR, and Dr. Anthony Hayward, Director, Division for Clinical Research Resources, NCCR, opened the meeting by introducing the representatives from the new and existing CTSA awardees, as well as the Trans-NIH members.

CTSA Program Scope and Budget Discussion

The Co-chairs of the Consortium Oversight Committee, Dr. Lars Berglund (UC, Davis) and Dr. Robert Califf (Duke Univ.), led a discussion of strategies for individual CTSA institutions to adjust their program scope to match the budget, as well as how to manage the budget across the entire consortium. NIH needs to support a sustainable national CTSA Consortium of 60 CTSA Awardees by 2012.

Regarding the funding challenges, representatives from NIH stated that they would work with each institution as they reassess their individual goals and scope. The CTSA Awardees of 2006 can provide the leadership to work as a consortium. NIH urged the institutions to be creative and flexible moving forward, including looking for ways to attract funding from other sources. Additional guidance on funding and rebudgeting can be found on the CTSA wiki page:

<http://ncrrctsa.ncrr.nih.gov/wiki/x/EIGX>

As an example of institutions facing similar issues in the current budget environment, Linda Weiss, NCI, provided insight into how the cancer centers are working to sustain themselves at lower funding levels. They have adjusted by re-assessing their priorities, as well as by identifying funding sources from philanthropic groups, industry, etc.

Susan Shurin, NHLBI, noted that IC Directors are not always aware of what clinical studies and trials are being supported by infrastructure programs, like the GCRCs and CTSA. The Directors are eager to figure out how to leverage the investments in the CTSA program. They are looking to see how their investigators use the CTSA such that they do not duplicate investments, and can appreciate the contributions from both the GCRCs and CTSA.

NIH has told academic institutions applying for CTSA funding for 2008 not to modify their applications based on the new budgetary model. For the CTSA applicants thereafter, there will be changes in the RFA. NIH representatives suggested that CTSA leverage each one's strengths (T1 translation, bioinformatics, etc.), and develop creative partnerships to increase cost efficiencies.

The CTSA Awardees of 2006 have written to Dr. Zerhouni, Director of NIH, to request a face-to-face meeting to discuss the funding situation. They hope that discussions from today's meeting further help to scope workable solutions to the current issues. The letter will be copied to the CTSA Awardees of 2007.

It was suggested that the PIs and their administrative staff schedule a conference call with NIH and include representatives from the NCRN Office of Grants Management. They should leverage discussions held during the CTSA Administrators Working Group Meeting. The PIs should develop and submit a specific list of questions for the Grants Management staff to review prior to the call. NCRN indicated that their Grants Management staff will continue to be open and available to discuss issues, including being available on monthly calls with the CTSA to discuss and answer questions. NCRN will continue to work with each institution on an individual basis as well.

In response to a concern over the budget situation, a representative from NCRN noted that the CTSA will be reviewed as a consortium. The CTSA can have significant influence if they act as a consortium, engaging the academic health centers throughout the program. In addition, if the consortium demonstrates that it can work together effectively, it may be able to attract funding for specific joint projects. It was suggested that the group identify scientific projects that demonstrate the strengths of the consortium.

Orientation to the Consortium

The group discussed IRB metrics that might be improved by consortium agreements between CTSA. The CTSA Alternative Pilot IRB Project Working Group is examining other IRB models as alternatives to single institution IRBs in order to improve implementation of clinical research protocols at multiple sites. The CTSA sites are working on metrics for IRB and contracts timelines to their public websites.

Anthony Hayward (NCRR) announced that the Management Support Center contract was awarded to Booz Allen Hamilton on October 1st and that Jody Sachs (NCRR) is the Project Officer for this contract.

Public-Private Partnerships (PPP) Steering Committee Presentation

Dr. Scheideler (NINDS) and Dr. Dewhurst (Univ. of Rochester) gave an update on the PPP Steering Committee. In June 2007, the group appointed 2 CTSA representatives (Steve Dewhurst from Univ. of Rochester and Bill Sandborn from Mayo Clinics - Rochester) as co-chairs

The Committee's topics focused on three major areas of interest: aggregation of IP and resources (identify common funding gaps and opportunities to fill them via PPP), agreements (identify rate limiting steps that constrain collaborative PPP agreements between CTSA members), and education (create shared curriculum reflecting CTSA consortium PPP needs, develop entrepreneurial awareness and skill sets in translational researchers).

The committee proposed to launch two working groups by aggregating IP and Resources and Agreements (both have high initial enrollment and depth of proposed activities). It was also proposed to continue to incubate an education Working Group in the committee.

A representative suggested that the program look to the Insurance industry to participate in the program, and possibly as a source of funding. For example, Oregon has been working with Kaiser Permanente to develop shared partnerships. Other CTSA members indicated that they had partnerships or relationships with the insurance industry. Other areas to pursue include pharmaceutical and biotechnology firms.

Communications Presentation

Dr. Kameha Kidd, the NIH Coordinator for the Communications Workgroup, provided an update on communications activities. The website, CTSAweb.org, provides publicly available information about the CTSA program. There is also a secured access wiki, where the content is driven by the CTSA committees. Dr. Kidd pointed out several key areas on the website, including the Communications Toolkit, access to the Governance Manual, and the weekly E-Newsletter.

Dr. Kidd walked the participants through the Wiki, the collaborative online work environment used to collect, share, and develop information. Goals of using the Wiki include fostering the goals of the CTSA Consortium, saving time and resources, and

reducing burden to collaboration. She pointed out some important features, including the front page dashboard. The Wiki is currently in a pilot phase. Users currently need the URL to access the Wiki, but it will soon be available through the website (CTSAWeb.org).

Discussion of CTSA Consortium Operations Workgroup (COC):

The group discussed the creation of the Operations Workgroup. The group will serve as a larger interface between the PIs and the NCCR, which will grow in importance as the consortium grows. It was suggested that an Operations subgroup of 15 people (10 CTSA PIs and 5 NIH voting members) would serve as the information filtering group. This will be discussed further during next month's PI call.

Regarding the structure of the Group, it was suggested that it have a staggered representation and that it should be a liaison with other working groups and steering committees so that the Operations Workgroup is aware of activities across the consortium. It was noted that it would be helpful to eventually have a workflow chart to illustrate how information is communicated among working groups and committees. PIs will need to communicate thoughts about the Operations Workgroup prior to their next meeting.

Topic Discussions from PIs

Dr. Tabak, Director, NIDCR, and Dr. Gallin, Director, NIH Clinical Center, addressed how CTSA's can interact with the NIH Clinical Center and vice versa. The Clinical Center's resources include patients with rare diseases, phenotyping (imaging, metabolic units, biomechanics lab), unique products (blood products, PET ligands), and a GMP facility to manufacture candidate agents.

Current opportunities include a testing site for new clinical research tools (patient surveys, simple informed consent forms, and informatics tools) and training (investigators, administrative managers, and nurses). Future opportunities include exchange of sabbaticals for clinical researchers and a bench to bedside program.

The Clinical Center can work with CTSA programs through hosting data sets and contributing other unique resources. There is a possibility for a CTSA/Clinical Center IRB consortium, and the CTSA could be a pre-made place where NIH could go to launch major new initiatives.

Welcome from the Office of the NIH Director

Dr. Raynard Kington, Deputy Director, NIH, presented his views on the growth and development of the CTSA program. He said that he was impressed by signs that the program is beginning to have an impact on clinical research. He noted that the CTSA program was evolving and that he thought it was going in the right direction. He was especially pleased with the range of partnerships pursued (minority, nonprofits, national laboratories, etc.), and said that the program is attracting attention throughout Washington, D.C., including with Congress and the FDA. He is pleased with how the

collective institutions can form a national consortium and is impressed with efforts to share resources, data, integrate intellectual resources, etc. and the openness to new approaches for IRBs and informatics.

Regarding the budget situation, Dr. Kington reminded the group that NIH has a large, complex mission with limited resources and competing demands. The budget planning process is extremely complex, negotiating and determining how to sort out where the streams of money should go and how to integrate those streams of money.

In response to a question about NIH institute leaders involvement and enthusiasm, Dr. Kington responded that to the extent the CTSA program evolves, other NIH institutes will develop more support for the program. He suggested the CTSA sites begin identifying a few pilot projects to demonstrate what the consortium can do. This can be accomplished by getting a good quick win, such as a program that can show it helped achieve results quicker and less expensively. When asked about extending support for K scholars beyond 6 years, Drs. Kington and Alving agreed to pursue the issue and to work towards trans-NIH uniformity.

Presentation On The Development Of Goals/Milestones For The Upcoming Year

The PIs suggested that the next meeting be a two-day face-to-face meeting. It should be held in December 2007 or January 2008, and could be located in the middle of the U.S. The meeting could focus on how to come up with early wins in the CTSA consortium. The group could come up with three to four separate topics (informatics, translational research, etc.) and ideas that highlight their strengths. The goal would be to develop a report of what has been accomplished collectively by the CTSA Consortium over a relatively short period of time. It is important to have a win in an area that the group has not had before, something that is unique to CTSA. Dr. Alving indicated support for the proposed meeting.

It was suggested that the group should leverage demonstration projects to show what it can do; this should not be done in a vacuum. The group should look at what NIH Institutes are planning with multi-center studies, and approach them and show them how the CTSA can help them get the study done more efficiently and at less cost.

Institutes do not realize how many of their studies are being subsidized by the GCRC/CTSA; therefore it is important to educate the institutes. There is an opportunity for institutes to conduct their training through the CTSA's (leverage the K12 infrastructure).

A participant stated that they do not think the CTSA consortium should be known for just being a clinical trials network. Earlier criticism seemed to focus on solely running trials for Institutions and it would be a shame if that is the greatest accomplishment for the CTSA consortium.

It was also noted that the group should involve their stakeholders, educating them on the CTSA program, give them a voice about what they would consider a success, and include those in the overall priorities. Patient advocates should be an integral part of the prioritization process. The group also talked about engaging communities. CTSA should go beyond what has been done in the past to include diverse communities.

Engaging the community is not an easy process, but CTSA's have an opportunity to do this by identifying best practices and using this to go forward.

It was suggested that the demo project focus on science, especially if the CTSA program is trying to engage the institutes (CTSA genotype-phenotype initiative). If the group sets up that infrastructure, it is an area where the group can be leveraged by other institutes.

The issue of cross partnering with DHHS Agencies was raised, such as with the FDA (aware of CTSA's and what they can do) and CDC (interested in CTSA, especially in training), AHRQ, and HRSA. Marc Walton from the FDA reinforced the close relationship they have with the NIH, saying although FDA is not a funding agency; it is very interested in the development of the CTSA Program and has a strong constituency behind its success as a Consortium.