

## **CTSA Consortium Oversight Committee Meeting**

January 15-16, 2008

5635 Fishers Lane, Conference Center Rooms T508-510  
Rockville, MD 20852

**Attendees:** L. Berglund, Co-Chair, UC Davis; R. Califf, Co-Chair, Duke; A. Hayward, NIH Coordinator, NCRR; E. Zerhouni, NIH; B. Alving, NCRR; J. Atkinson, NIDCR; T. Beck, NCRR; E. Collier, NCRR; M. Corn, NLM; L. Derr, NCI; G. Farber, NCRR; R. Filart, NCRR; W. Goodman, NIMH; F. Grieder, NCRR; I. Grissom, NCRR; S. Haldane, IHS; M. Heiskanen, NCI; K. Kidd, NCRR; C. Lomonaco, NCI; W. Martin, NIEHS; D. McCloskey, NCRR; S. McClure, NCRR; W. McCullough, NCRR; S. McNairy, NCRR; C. Merchant, NCRR; L. Mulligan, NCRR; P. Newman, NCRR; I. Obrams, NCRR; G. Pearson, NHLBI; D. Rosenblum, NCRR; J. Sachs, NCRR; A. Sawczuk, NCRR; M. Sayre, NCRR; D. Sheeley, NCRR; S. Shurin, NHLBI; B. Smothers, NINR; J. Stanford, NCRR; B. Tai, NIDA; B. Talbot, NCRR; A. Trachtenberg, IHS; L. Weiss, NCI; D. West, NCRR; D. Wilde, NCRR; F. Arnett, Texas; G. Bernard, Vanderbilt; D. Clauw, Ann Arbor; B. Collier, Rockefeller; P. Davis, Case Western; M. Disis, UWashingon; M. Drezner, UW-Madison; G. FitzGerald, UPenn; D. Ford, Johns Hopkins; H. Ginsberg, Columbia; D. Guzik, Rochester; G. Hunninghake, Iowa; J. Imperato-McGinley, Cornell; D. Jacoby, OHSU; M. Joyner, Mayo; M. McCune, UCSF; V. Montgomery Rice, Meharry; E. Ofili, Morehouse; M. Packer, Dallas; T. Pearson, Rochester; K. Polonsky, Washington U; S. Reis, Pittsburgh; D. Robertson, Vanderbilt; J. Rush, Dallas; J. Sands, Emory; R. Sherwin, Yale; J. Slattery, UWashingon; J. Solway, Chicago

### **January 15, 2008**

#### **Discussion of specific issues for Dr. Zerhouni per the summary points from the December 10<sup>th</sup> call/CTSA Consortium Discussion**

The CCOC meeting started at 12 noon. Dr. Alving updated the PIs on the budget and outlined NCRR's objectives for the current meeting, which included increasing the involvement of PIs in specific CTSA committees, identifying a nominating group and charging them with implementing nomination of the next CCOC co-chairs and a CCOC Operations Group that will enhance timely management and communications. The importance of sharing best practices with each institution was also noted.

The PIs discussed the role of regional activities among CTSA's, such as Yale and Rockefeller's upcoming joint symposium. Regionalization could break down silos locally. Interactions between NCRR's \$200M Institutional Development Award (IDeA) program and CTSA's in areas such as proteomics could bring people together from different intellectual domains.

The PIs discussed the long term goals of the Consortium. One idea was to focus on helping awardees streamline clinical research processes at each institution and share best practices to shorten protocol implementation time. Another idea was to identify a research area for cross-CTSA collaborations. The need for metrics to measure resource

input/output was stressed by some members, as well as the need to be aware of successes and failures at specific institutions.

The group agreed to identify a pilot issue to move forward. A national phenotype project was mentioned as a possibility for this because of the existing infrastructure, and it was decided that this should be put to paper in order to have a substantial discussion about the issue. It was recommended that the CCOC Operations Group work with the NIH in this area.

Dr. Alving mentioned that the NCRN Council meeting on January 30, 2008 would be a good opportunity for CTSA to present what they are doing. She also stated that there is a common fund out of the Office of Portfolio Analysis and Strategic Initiatives (OPASI), where there is a phenotype expertise and interest that is being sought.

The importance of setting and reaching goals was stressed by numerous members and the CCOC will ask the Operations Group for a significant planning effort. One member said her institute had hired an outside group to help with internal organization, which had resulted in setting a stage where everyone understood what the major areas for success and failure were. Another member said their institution has a department solely devoted to planning and systems/procedures.

Dr. Alving stated that NCRN was very supportive of getting this expertise and using it to organize this consortium so it has real sustainability. She suggested the CCOC come up with proposals, NCRN will determine if they have it within its budget to support it, and if so, NCRN can take the proposal to Dr. Zerhouni.

Utilizing the ICs at NIH was discussed. It was stated that the ICs need to be aware that the CTSA's are in a forward-thinking mode, and the CTSA's need to communicate their value to the ICs, mainly through determining how to do things better and show efficiencies.

### **Working Lunch with presentation of pre-meeting discussions**

Dr. Sherwin volunteered to form a nominating committee to identify candidate co-chairs for the CCOC and to establish an Operations group (a group of PIs who would provide advice and help with the immediate management of the CCOC). The nominations for the co-chairs should be completed by the next CCOC face to face meeting in April. The CCOC recommended that the Operations group be expanded to function as an Operations/Planning group. The group will have 10 members, seven from CTSA's and three from NIH.

It was suggested that the CCOC create a public private partnership with a company like Microsoft, Google, or IBM. NCRN stated that these partnerships are welcome, though they would have to be open and transparent. It was noted that the PPP Steering Committee is currently working on standard practices for these proposed partnerships.

One endpoint by which CTSA success can be measured is in the output of trainees. The biggest roadblock to the program is the limitation of human capital of people who

have interdisciplinary skills. It was proposed that the group think about whether there is a need for one or two disciplines to emerge as a magnet to attract people to train in interdisciplinary science.

### **Presentation by Dr. Elias Zerhouni, followed by discussion**

Dr. Zerhouni told the PIs that he was looking for their leadership in this new academic specialization. He sees CTSA as change agents that should develop a new U.S. model of translational and clinical research based on the scientific requirements of today. He stated that there is tremendous support for translational science, both T1 and T2, and that academic centers should not be isolated from their community.

Dr. Zerhouni urged the CCOC to prioritize what they will accomplish in five years, 10 years, etc. It is important to develop a different model of government for clinical research, and the progress is going to be heavily dependent on CTSA's ability to do this. Dr. Zerhouni's hope is that there will be 24 different approaches to compare and that in five years, the best practices from the institutions get adopted by everyone else.

Dr. Zerhouni suggested that the PIs create a focus area, a "common core", so he can convince Congress to increase its investment in the program. The group needs to act as a differentiated class of scientists and needs to have a defined curriculum, ideally a national curriculum. In addition, it would be helpful if the group could provide solutions for how they are going to ensure safety and effectiveness, technologically and/or functionally.

The PIs told Dr. Zerhouni that they had decided to engage in a secondary planning process with a smaller Operations/Planning group that will work with an outside party. Dr. Zerhouni agreed that this should be the group's top priority and that they create a CTSA action grid for future objectives.

Dr. Zerhouni said he was more than willing to put political capital on the table to ensure there is synergy among the PIs. He also said that the CCOC had to have its own internal outcomes. He noted that the group should keep in mind the synergies with other institutes, as they really want CTSA to succeed.

### **Breakout group sessions**

- [Attachment A](#) – Promotion of Growth of Cadre of New Investigators – Education, Funding Flexibility
- [Attachment B](#) – Priorities of CTSA Informatics Consortium – CTSA Informatics Steering Committee
- [Attachment C](#) – Clinical Research Management – Metrics, Standards/agreements for IRB, Contracts, Workforce Education and Competency

**January 16, 2008**

### **Reports from breakout groups**

The Education breakout group session was summarized (see [Attachment A](#)). Discussion raised the interest of the FDA and perhaps the NIH in promoting short courses in clinical research. The possibility that the Wellcome Trust might sponsor a meeting on a core curriculum in 2008, depending on input from academia, industry, and regulatory bodies. Instead of calling for a unified curriculum, a set of core competencies was suggested. Accreditation may be worth discussing.

### **Budget Discussion**

PIs had several questions about the management of TL1 and KL2 budgets. Irene Grissom (Director, NCCR OGM) explained that the TL1s were governed by NRSA rules while KL2 management was subject to NIH policy. Dr. Alving agreed that NCCR would provide additional guidance on carryover requests. When awardees request a carryover they should expect a response from NCCR within 30 days.

### **Discussion on mechanisms to identify and develop Trans-CTSA Projects, with a focus on Translational Science**

Dr. Susan Shurin, Deputy Director, NHLBI, spoke on aligning infrastructure with research questions (see in [Attachment D](#)). Categorical institutes generally have existing mechanisms to support their clinical research that could use institute-specific or institution-based resources such as organized investigator communities. She felt that many of the delays encountered when starting up a study could be eliminated if the investigators had increased resources or skills, as might come from a CTSA. These include better access to patient populations and to the general population (community-based research on common diseases). Possibilities of CTSA leadership from NHLBI's point of view:

- CTSA infrastructure could enable categorical institutes to conduct studies more rapidly without having to build and disassemble
- CTSA could provide education and to improve conduct of clinical research in the U.S.
- Central IRB for NIH-funded studies
- Informatics systems which talk to each other or a common system

Dr. Shurin stated that it would help to create a culture within the broader population as a whole that is more trustful of clinical research.

Regarding RFAs coming out only to the CTSA's, Dr. Shurin stated it is highly probable that NHLBI will put out RFAs to the larger community, but institutions with CTSA's might have a competitive advantage. All NIH Institutes are constrained by the budget environment and a continuing dialogue with CTSA's would be helpful. For the NCI, Dr. John Niederhuber is interested in establishing a connection with CTSA's. The Cancer

Center's program has been going on for 40 years, so infrastructure has been in place for a long period of time.

It was suggested that one CTSA PI be identified as a liaison for each categorical institute, and through that person, PIs can make suggestions in areas where the network can be leveraged for application to each particular institute. The PI liaison could attend Council at that particular institute to share information.

### **Reports from breakout groups (continued)**

The Clinical Research Management breakout session is summarized in [Attachment C](#).

Participants favored public reporting of their metrics after internal review. There was overwhelming support for the June 23-24 workshop, as well as this taskforce going beyond the first steps advocated for the meeting.

The Informatics breakout session was summarized (see [Attachment B](#)).

The Informatics White Paper was highly recommended as a good resource. It is posted on the Wiki.

### **Working Lunch**

PIs agreed that they would self-nominate for involvement in Steering Committees and Workgroups by email, listing their first, second, and third choices for Drs. Berglund and Califf.

Important upcoming dates:

- January 2008 – CTSA program update
- Feb 2008 – New review cycle starts
- July 2008 – Next awards anticipated
- June 17, 2008 – Applications for 09 awards
- March and July 2009 – FY 2009 awards anticipated

The next PI meeting will be scheduled for the end of April.

### **Discussion: How should the CTSA consortium be evaluated?**

Lori Mulligan gave a presentation on the framework for evaluating the consortium ([Attachment E](#)).

National evaluation will focus on the collective contributions of the consortium. Over time, the consortium will contribute success toward fulfilling priorities, milestones, and goals set by the consortium and RFA. The effectiveness, adaptability, and responsiveness of the governance structure, along with the effectiveness of methods used to foster collaboration, will be used to evaluate the consortium.

Consortium activities are analyzed through strategic plans, interviews with PIs and Committee Chairs, workshop outcomes, meeting summaries, ctsaweb.org and CTSA Wiki, and aggregated information from annual progress reports. They are tracked by External Advisory Board assessments of Consortium contributions, interactions, and collaborations. Internal and external stakeholders are interviewed to ascertain perceptions of the Consortium's effectiveness and involvement.

### **Summary and Key Action Items Review**

1. Dr. Sherwin is the chair of the nominating group for the next co-chairs, and the Operations/Planning group. He will need two or three PIs to join him on this committee.
2. All CTSA committees would like to have two PIs actively involved. Each PI needs to submit their first, second, and third choices to Drs. Berglund and Califf.
3. Follow-up on Dr. FitzGerald's suggestion to have a PI interface with Council at categorical Institutes. Dr. FitzGerald will send a summary email to everyone and will solicit from CTSA PIs programmatic relevance that would leverage the CTSA. Dr. Alving offered to reach out to other IC directors about this.
4. The PIs will send their choices about which categorical Institutes they want to interface with to Drs. Berglund and Califf.
5. Post slides to MS and Wiki from Dr. Shurin's presentation.
6. Post breakout session summaries to the Wiki. Summary of breakouts should go to the CTSA and NIH chairs first prior to getting posted on the Wiki.
7. Drs. Collier and Califf will have a writing group, and Dr. Collier will send out the section of their grant to everyone.
8. Dr. Ginsberg will send out an email to everyone asking for the amount of money left over in their K12.
9. Write a proposal for organizational planning support. Dr. Joyner volunteered the head of planning services at Mayo, Steve McNeal, to help with this proposal effort.

Meeting adjourned at 2:05pm.