

CTSA Consortium Steering Committee Meeting

March 17, 2009

1:00pm-2:00pm

Attendees:

G. Bernard, Vanderbilt; G. FitzGerald, Penn; B. Alving, NCRR; R. Califf, Duke; D. Center, Boston; R. Clark, San Antonio; N. Disis, Washington; D. Ford, Johns Hopkins; L. Guay-Woodford, Alabama; A. Hayward, NCRR; G. Hunninghake, Iowa; D. McClain, Utah; L. Nadler, Harvard; M. Packer, Texas; K. Pienta, Michigan; E. Pisano, UNC; K. Polonsky, S. Reis, Pittsburgh; H. Shamoon, Einstein; R. Sokol, Denver; J. Solway, Chicago; D. Stephens, Emory

ARRA Challenge Grant

Dr. Alving presented an update on the amount and distribution of ARRA funding and noted that administrative supplements will be announced on the NIH website in the near future. Funding opportunities range from administrative supplements of R01 awards to revisions (competing) supplements, which allow changes in scope, and RFAs targeting specific IC scientific areas of interest.

The National Center for Research Resources is listed for five challenge grants that cover topics including Informatics, and Comparative Effectiveness Research (CER). On questions related to funding for CER, Rosemarie Filart will respond to queries. Mary Purucker will clarify the process for Child Health-related administrative supplements funding in a forthcoming letter to CTSA PIs and Administrators.

Strategic Goal Committee 1 – Clinical and Translational Research Management Capability

Dr. Dan Ford reported on the groups working on two protocols in IRB and contracts under this Committee, noting that not all sites are represented. The “Champions of Change” initiative, which requests that each CTSA site identify a leader who has the authority and motivation to energize the members of the site’s IRB and contracts offices to provide optimal data collection and reporting, is underway. Vanderbilt University’s Redcap system is to serve as the data collector and the two groups are in partnership with various sub committees to standardize the collected data and to identify ways to present these metrics to the public. Five representatives of the Champions of Change will review data and a PI is asked to volunteer to participate in this review.

It was noted that ARRA funds may help with this effort, however, it is important to set timelines to enable transparency into the process and the expected outputs. The Gantt Charts, when completed, would serve this purpose and provide information on the work of the CTSA to the public.

Members noted that this data collection effort is a tremendous undertaking, and that in addition to data on the IRB process a map illustrating the entire end-to-end course is needed. One member suggested the usefulness of incentives such as participation in this data collection initiative could be used as a factor in the institution's renewal application; another noted the need for resources to be refocused in the regulatory knowledge area. These "champions of change" are expected to participate in a CRM Workshop on June 22 – 23, 2009.

Strategic Goal Committee 2 - Training & Career Development of Clinical and Translational Scientists

Gary Hunninghake shared the implementation underway in the three areas that this Committee is focused on:

1. Core curriculum addressing the needs of clinical and/or translational investigators
2. Core competencies for clinical and translational investigators
3. Career Mentoring

Dr. Frederick Oghnibene will join as a Trans-NIH coordinator for this Committee.

Strategic Goal Committee 3 - Enhancing Consortium-Wide Collaborations

Dr. Harry Shamon reported that the initiatives underway are on track and that the Research Networking subgoal group has called on resources from across the consortium to assist with its planning and activities. To ensure collaboration between SGC 3 and SGC 4, the Data Sharing and Research Network Subgoal groups will hold a call on March 18 and present their report to SGC 4.

The next SGC 3 call is scheduled for Wednesday, March 25 and the agenda will be to integrate inventory and data sharing subgoal groups. A report from this meeting will be shared with the Steering Committee in April.

Strategic Goal Committee 4 -- Enhancing the Health of Our Communities and the Nation

The activities under strategic goal 4a: "Link and facilitate collaboration among community-based research networks to implement research and best practices" are well underway as these were developed under the Community Engagement Key Function Committee and much preparation has been completed.

Under strategic goal 4b: "Develop capacity and methods for the translation of research results into practice across the healthcare system, including but not limited to health services and health policy research, comparative effectiveness research, and research into the generation and implementation of evidence-based medicine," efforts are underway to address how CTSA's can act as a portal to facilitate comparative effectiveness research for ICs in comparative effectiveness research

There are plans for four deliverables to address how translation of research can have a positive impact on comparative effectiveness research (CER). The CER Interest Group will elicit input from the rest of the Consortium and more information will be forthcoming.

Discussions centered on how the CTSA can work with the Challenge Grants on CER. As there is tremendous interest in this issue, applicants should mention work with CTSA's in their application. In addition, members should consider best practices and post these to the NIH. As this is time sensitive, those interested should present ideas in the next week.

Other Business

Translational Goal: Dr. Kenneth Polonsky reported that there have been a number of calls with the Translational KFC and that the chief challenges are definition and scope as there is no consensus on what translational research should cover. The KFC has drafted a white paper which outlines the common vision, and then key projects will be developed before moving forward to the next step of recommending that this issue become the fifth CTSA Strategic Goal. Translational issues, including phenotyping, which is the interface of T1 and T2, will have an impact on the work of SGC 3, therefore, it is expected that the Translational KFC (or SGC) work with SGC 3 on feasibility study or demonstration projects.

The white paper will be forwarded to the Steering Committee in the near future and the recommendation is expected to move forward with creating a fifth SGC to address this issue. The focus would likely be on the nuts and bolts of science projects in T1 research and how to move methodologies into clinical trials – how to go from bench to bedside.

Dr. Alving expressed her endorsement of T1 issues to become SGC 5 as there is much interest from NIH as well as the Human Genome Institute in T1 studies. She noted that Dr. Susan Old, Senior Advisor to NCCR, has been asked to serve as the NIH Coordinator on this effort and to help catalyze T1 research in CTSA and other programs. Dr. Polonsky noted that efforts are underway to define projects and timelines.

On the SGC Overview and Gantt Charts that have been sent, Dr. Hayward noted that these are drafts and are open to input and comments.

Action Items:

- Provide timelines and populate the Gantt Chart to reflect work underway and plans going forward (All SGC Chairs)
- Present ideas and best practices on CER to NIH (All)
- Provide white paper and recommendations on T1 Translational Research to the Steering Committee (K. Polonsky/D. Sheeley)

The meeting adjourned at 2:00pm.