

## OVERVIEW OF STRATEGIC GOAL COMMITTEE ACTIVITIES May 2010

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## **SGC #1 -- National Clinical and Translational Research Capability**

PIs: Jim Heubi (PI Lead), Bruce Cronstein, Hugh Sampson

Administrators: Kim Toussant, 2 others TBD

CMG Liaison: Anne Willoughby

NIH Coordinator: Dan Rosenblum

Booz Allen Hamilton Project Manager: Tanya Buttress

### **Meeting(s) Held:**

- Three meetings held to-date in 2010, latest was May 11, 2010
  - Three PIs have been selected for SGC#1: Jim Heubi (Cincinnati, PI Lead - serves on CCEC in 1st year), Bruce Cronstein (NYU, PI, serves on CCEC in 2nd year term), and Hugh Sampson (Mount Sinai, PI, serves on CCEC in 3rd year term).
  - Kim Toussant, Administrative Director at Ohio State University, currently serves as CTSA Administrator on SGC#1. The other two potential Administrative positions remain vacant.
- SGC #1 Subgroup(s)
  - The Co-Chairs of the Champions of Change Groups have completed their individual interviews with each Champion of Change at their counterpart CTSA sites. They have scheduled a web conference for June 7<sup>th</sup> to develop a status report on the CRM IRB and Contracts initiatives, describe their one-on-one interviews with the Champions of Change, and prepare for participation by the Champions of Change in the 3rd Annual Clinical Research Management Workshop, June 21-22, 2010.
  - The Metrics, Analysis, and Mapping (MAM) Group had a Face-to-Face Meeting on March 18<sup>th</sup> at which they discussed the best use of the existing IRB Pilot Study data results, plans to publish the results, and future studies on protocol processing. The MAM Group is drafting a protocol for the next IRB study.
- Clinical Research Management (CRM) Key Function Committee and Subgroups (the CRM KFC delegates all its tasks to subgroups)
  - The 3rd Annual Clinical Research Management Workshop will be held on June 21-22, 2010 at the Bethesda North Marriott Hotel & Conference Center in Bethesda, MD. The registration website, agenda, and logistics can be accessed at <http://ycci.yale.edu/conference/>. This year's Workshop will focus on implementation of change in protocol and contracts processing and improvement in recruitment and retention. A publication is in progress for the 2009 2<sup>nd</sup> Annual Clinical Research Management Workshop.
  - The Contracts Subgroup has submitted the data from the Contracts Pilot Study to the MAM Group. The Second Contracts Study is expected to be completed by October 2010. The subgroup plans to present a brief report of Pilot Study 2010 CRM Workshop and to publish results of the Second Contracts Study in 2011.
- Regulatory Knowledge Key Function Committee and Taskforces
  - CTSA Regulatory Knowledge Key Function Committee members proposed having a face-to-face meeting in addition to the smaller meetings at the June CRM Workshop

2010. The KFC reached a consensus; it has plans to pursue many topic areas; focus requires an in-person meeting. Below are Taskforce updates:
- Research Subject Advocacy (RSA) Taskforce: It held a call on April 29 and fielded its survey on Monday, May 3, 2010. It remains for the Taskforce to decide to whom its surveys should be distributed; the voting members of the KFC may not be in an optimal position to respond. The Taskforce decided to send the surveys to voting members, wait a week for a response, and, if no response is received, send the survey to a listserv or conduct individualized follow-up.
  - Clinical Trial / Study Registration Tracking Taskforce: The Taskforce has had extra meetings in order to focus on the analysis of the results of its surveys. They will be meeting again in May to finish the analysis and prepare a poster for the CRM Workshop. Taskforce members are also trying to prepare a white paper. The Taskforce plans to review the preliminary data at the CRM Workshop.
  - IND-IDE Taskforce:
    - A publication “The Clinical and Translational Science Award (CTSA) Experience” was accepted by Academic Medicine for publication on February 9, 2010. Taskforce members will conduct discussions on sharing of tools and best practices; it will also provide its recommendations on a poster for the 2010 CRM Workshop.
    - The GLP subgroup is active; it has written a draft for a paper and prepared a poster for the CRM Workshop. They expect the paper to provide content for the poster and will use reaction to the poster to inform the draft. Please contact Eric Rubinstein if there are suggestions for material to include in the document.
    - Finally, the FDA has asked for comments regarding a Guideline: Reporting Information Regarding Falsification of Data: <http://edocket.access.gpo.gov/2010/pdf/2010-3123.pdf>. The IND/IDE Taskforce has written a draft response. The CCEC voted to approve the letter which will be written on CTSA Consortium letterhead but be issued by the IND/IDE Taskforce. The response letter is due before May 20; the group plans to send it to the members of the Regulatory Knowledge Key Function Community in its final form. Members with comments have been asked to send them to Karen Hartman, the IND/IDE Chair.
  - Clinical Research Coordinator (CRC) Taskforce: The CRC Taskforce has been subdivided into three groups.
    - Publication: This group will summarize the results from the surveys to prepare for a white paper. Monday, May 3, the draft was to go to the entire the CRC Taskforce. The Taskforce hopes to have a draft for the full KFC by the end of May.
    - Job Description: This group is working to meet the poster deadline for the 2010 CRM Workshop.
    - Education/Training: The next meeting is on May 5 at 10 am ET to review the surveys that were sent to Taskforces on the types of training the CTSA's have in place. The group is also planning on webinars on development and implementation of employment training plans.

- **Recruitment and Retention Taskforce:** This Taskforce had 44 of 46 institutions responding to its survey. It is working on data analysis. The Taskforce plans an oral presentation and poster for the 2010 CRM Workshop. The investigator level survey is still open. One third of the institutions have received the investigator link.
- **The Core Competency Taskforce:** In consultation with the Clinical Research Ethics KFC, the Taskforce drafted core competencies for inclusion in the set of recommendations drafted by the Education and Career Development KFC. These competencies integrated previous competencies developed independently by Regulatory Knowledge and Research Ethics. The Taskforce forwarded its recommendations to the Education and Career Development KFC on 3/18/2010 for review before vetting by SGC 2.
- **CRMS Taskforce:** Members were interested in the Taskforce, but undecided with respect to its definition, focus, and deliverables. They agreed to meet face-to-face in order to seek consensus on its plans and goals. Jody Sachs, Rhonda Kost and Katherine Schuff plan to have a face-to-face meeting on June 21<sup>st</sup> from 3:45-5:00 pm at the 2010 CRM Workshop. The group plans to create a plan to develop consensus on the deliverables.

**Meetings Planned:** The SGC#1 Group meets on a bi-monthly basis beginning with January on the 3<sup>rd</sup> **Wednesday from 12:00 – 1:00 PM ET.** The next SGC#1 meeting is planned for **Wednesday, July 21<sup>st</sup> at 12:00 PM ET.**

### **SGC #2 – Training and Career Development**

PI Co-Chairs: Tom Pearson  
NIH Coordinator: Carol Merchant  
Booz Allen Hamilton Project Manager: Kevin Johnson

#### **Meetings Held**

The meeting during the month of April was cancelled. The group will reconvene in May. Possible agenda topics include:

- New Governance Plan for SGC #2 (Bushra Rehman)
- NIH-CTSA Forum Consensus Recommendations Update ( Dr. Merchant)
- Core Curriculum Mapping Project Update (Drs. Dilmore and Pearson)

#### **Core Curriculum Working Group**

The Core Curriculum Working group was formed during the month of March. This group was also a recommendation that arose from the SGC #2 meeting in January of 2010. The overarching goal is to develop core curriculum that could be made available to all institutions – even those that are outside of CTSA. The mapping of curriculum will build on the already developed NCERP education resources and courses available through the NIH Clinical Center.

At the group's recent meeting, Co-Chair Dr. Terri Dilmore proposed an activity for the group to choose two competencies from the NCCR Competencies Document to map against a course offering from the NIH Clinical Center. The purpose of this activity is for each group member to individually map the competencies and sub-competencies (objectives) against a specific course to determine if everyone agrees on the competencies gained from the course.

The group chose to map the Clinical and Translational Research Questions and Study Design competencies against the Introduction to the Principles and Practice of Clinical Research course. Instead of mapping the entire course, the group agreed to map only the Introduction, Modules I, and Module II. For each sub-competency or objective, each participant will decide if it is fully covered, partially covered, or not covered in the course using a template that Dr. Dilmore will be circulating to the group. Also the group will review an end of course exam (the only assessment for the course) and determine whether the objectives are partially, fully or are not covered through the exam.

#### Meetings Planned:

- SGC #2 Monthly Teleconference (May 26, 2010 – 3:00-4:00 PM ET)

### **SGC #3 – Enhancing Consortium Wide Collaborations**

Co-Chairs: Gordon Bernard, Steve Reis, and Anantha Shekhar

NIH Coordinators: Elaine Collier and Michael Sayre

Booz Allen Hamilton Project Manager: Kevin Batista

#### Meetings Held:

- *The SGC #3 Committee met via teleconference on May 4, 2010.*
  - The SGC #3 Committee discussed potential new areas of focus in Enhancing Consortium Wide Collaborations. It was felt that many national activities were ongoing in research networking and resource discovery, including the recently funded VIVO and eagle-i projects. The committee felt that following and keeping informed about these projects would be appropriate at this time. However, discovery by investigators at CTSA of opportunities for participation in new collaborations recently occurred by emailing these opportunities between CTSA PIs, who passed them to appropriate investigators at their CTSA. However, other options could be explored for facilitating these collaborations. In addition, it was pointed out that it was unclear how non-CTSA organizations, investigators, industry would approach the national CTSA consortium about collaboration. Also what types of collaborations with others should be sought by CTSA consortium deserved discussion and definition. Developing a consortium wide process would be helpful to both those wishing to collaborate with the CTSA and those in CTSA.
  - The SG #3 Committee decided to approach the CTSA Steering Committee co-Chairs about discussing this change in focus with the other PIs on the CTSA Executive Committee and the entire CTSA Steering Committee to elicit their response to this change in focus and additional ideas.

- The SG#3 Committee also invited the co-chairs of the Communications KFC to join their monthly call along with the co-chairs of the Informatics KFC to provide topical expertise.
- Tom Fogg provided an overview on the CTSA Governance document as it relates to Strategic Goal Committees.
- Michael Kahn and Dan Masys, the co-chairs of the Informatics KFC, provided a status update on their committee.
- *May 18, 2010 SG #3 Co-Chairs presented to the CTSA Executive Committee*
  - The SG#3 co-chairs presented their ideas to the CTSA Executive Committee at their May 18 meeting. The response was positive and the SG#3 co-Chairs will discuss this with the CTSA PI Steering Committee on their upcoming May 25 call.

**Meetings Planned:** The SG#3 Committee will present their ideas for new focus at the upcoming CTSA Steering Committee meeting. The SG33 Committee has a standing meeting on the 1<sup>st</sup> Tuesday of each month at 2 PM ET. The next SG#3 meeting will occur on Tuesday, June 1, 2010.

#### **SGC #4 -- Enhancing the Health of Our Communities and the Nation**

**PI Co-Chairs:** Drs. Harry Selker (Tufts) & Philip Greenland (Northwestern)

**NIH Coordinator:** Dr. Donna Jo McCloskey (NCRR)

**Booz Allen Hamilton Project Manager:** Kristin Kennedy

#### **SGC 4: Enhancing the Health of Our Communities and the Nation**

##### **Recent Progress**

Key decisions are as follows:

- A face-to-face meeting for the purpose of further developing networking connections has been planned for May 27, 2010 at Natcher Conference Center. This meeting will involve participants from federal agencies, representatives of various research networks, and other key thought leaders. Currently, there are 77 registered participants for this meeting. Planning continues for the meeting and additional invitations are being distributed as needed.
  - An add-on face-to-face meeting sponsored by NIDA will be held on May 26, 2010 to discuss strategies for advancing drug abuse research and collaboration with CTSA's. (<http://www.seiservices.com/nida/1014074/Default.aspx>).
  - An add-on meeting to involve federal agencies and other stakeholders in a discussion about the role of CTSA's in CER is being held on May 28, 2010 from 8:00 AM – 12:00 PM at Natcher Conference Center. The meeting will include approximately 18 participants and will be a precursor to a larger CER Stakeholders meeting to be held in October 2010. The points of contact for this meeting are Tom Concannon ([tconcannon@tuftsmedicalcenter.org](mailto:tconcannon@tuftsmedicalcenter.org)) and Eric Vidal ([vidal\\_eric@bah.com](mailto:vidal_eric@bah.com)).

- Per the recent changes to the CTSA governance document, the deliverable workgroups under the SGC4 have been moved to the associated Key Function Committees. For the SCG 4A Community Engaged Research Workgroup, the deliverable workgroups have moved to the Community Engagement Key Function Committee (CE KFC). For the SGC 4B Comparative Effectiveness Research Workgroup, deliverable workgroups have moved to the Comparative Effectiveness Research Key Function Committee (CER KFC). Each KFC will integrate the active deliverables and establish regular communication channels with the SGC by October 2010.

#### Status of former SGC 4 Deliverable Workgroups:

- **SGC 4: Combined Networking Group (formerly the SGC 4A-1/4B-4 groups):**
  - **The work of this group continues within the CE KFC.**
  - A face-to-face meeting for the purpose of further developing networking connections has been planned for May 27, 2010 at Natcher Conference Center. This meeting will involve participants from federal agencies, representatives of various research networks, and other key thought leaders. Currently, there are 77 registered participants for this meeting. Planning continues for the meeting and additional invitations are being distributed as needed.
  - The Workgroup has developed a web-based, searchable database from the Connections Excel spreadsheet. This website, called Com Net, is currently under refinement and is being built by a cross-functional team from the Community Engagement, Informatics, and the Communication KFCs.
- **SGC 4A-2: Best Practices in Community Engagement Subgroup**
  - **The work of this group continues within the CE KFC.**
  - The Best Practices in Community Engagement Subgroup is currently working on a first draft for an article that will be an overview of best practices for the CTSA Community Engagement consortium. This group is now working to collect examples of practical implementation strategies to support the implementation of the identified best practices. Additional assistance with this project will be sought from amongst the CE KFC membership.
- **SGC 4A-3: Administrative Supplements Subgroup**
  - **The work of this group continues, but there will no longer be an associated workgroup. Updates will be provided as necessary to the CE KFC.**
  - The Administrative Supplements Subgroup comprises two projects, the PRIMER and the Community Engagement Consult Service. The main objective of the PRIMER project was to identify and address research infrastructure needs that were commonly reported by Clinical and Translational Science Awards (CTSA) representatives, and those in Practice-Based Research Networks (PBRN). The Community Engagement Consultative Service (CECS) is designed to provide each CTSA with an expert consultant(s) in community engagement to address the CTSA's identified CE best practices of interest and need.
- **SGC 4A-4: Principles of Community Engagement Subgroup**

- **The work of this group continues within the CE KFC.**
- The Principles of Community Engagement Subgroup is working on a third draft of the revised CDC Principles of Community Engagement publication, with a tentative final draft completion date of July 2010.
  
- **SGC 4A-5: [Community Engagement Translation White Paper Committee](#)**
  - **The work of this group continues within the CE KFC.**
  - The [Community Engagement Translation White Paper Committee](#) is drafting a white paper to better define translation from the perspective of community engagement. This group has developed a straw person outline of the white paper, which was vetted on a group call. Currently the group is breaking up into smaller groups of volunteers to work on different sections of the paper. The group ultimately hopes to work towards publication in the peer reviewed literature.
  
- **SGC 4B-1: CER Needs Assessment Deliverable Workgroup**
  - **The work of this group will continue within the CER KFC.**
  - The CER Needs Assessment Deliverable Workgroup is planning to repeat the Needs Assessment survey with the current full membership of 46 CTSA institutions during the summer of 2010.
  
- **SGC 4B-2: CER White Paper Deliverable Workgroup**
  - **The work of this group is complete and the group has been sunsetted.**
  - The CER White Paper Deliverable Workgroup has completed its white paper, which was published by the Clinical and Translational Science (CTS) journal (<http://www3.interscience.wiley.com/cgi-bin/fulltext/123302740/HTMLSTART>).
  
- **SGC 4B-3: CER Methods Deliverable Workgroup**
  - **The work of this group will continue within the CER KFC.**
  - The SGC 4B-3: CER Methods Deliverable Workgroup is currently making updates to its deliverable, "A CER Methods Agenda for the CTSA Program," which is very near completion.
  
- **SGC 4B-5: CER Workforce Needs Deliverable Workgroup**
  - **The original deliverable from this group is complete, but the group will continue within the CER KFC.**
  - The CER Workforce Needs Deliverable Workgroup has completed their deliverable, entitled "Education and Career Development for Comparative Effectiveness Research (CER) Workforce Development." The report has three parts: 1) workforce needs and gaps for CER, 2) requisite competencies for CER, and 3) developing mechanisms to support training in CER. The group will incorporate recommendations from this work for training and education for core competencies.

- This group will continue as a part of the CER KFC because workforce needs and development has been identified as a critical issue for the CER KFC.

**Meetings Planned:**

The SGC 4 meets on a monthly basis beginning on the 4<sup>th</sup> **Monday from 11:00 AM – 12:00 PM ET**. The next SGC4 meeting is planned for **Monday, April 26 at 11:00 AM ET**.

An SGC 4-sponsored face-to-face meeting entitled “Network of Research Networks” will be held at the Natcher Conference Center, NIH Campus, Bethesda, MD on **May 27, 2010 from 7:30 AM to 4:30 PM**.

**SGC #5 T1 Translational Research**

PI Co-Chairs: Dr. Kenneth Polonsky, Dr. Nora Disis, Dr. Donald McClain  
NIH Coordinators: Heng Xie, Renée Joskow, Lili Portilla, Doug Sheeley  
Booz Allen Hamilton Project Manager: Sum Mehrnama

**Meeting(s) Held:**

- The monthly meeting for April was held on April 30, 2010.
- Dr. Daniel Sullivan, of Duke University, presented on the work of the CTSA Imaging Working Group (IWG). The IWG falls under the umbrella of the Translational Key Function Committee, however operates independently of that KFC. Among topics discussed were the thought that the consortium would benefit from greater interaction between imaging informatics and informatics in general.
- Becky Moen, of the Consortium Management Group (CMG), presented on the role of the CMG and also on some of the revisions to the CTSA Governance Document, and their impact on SGC 5. Through this discussion, the PIs decided to have Dr. Polonsky serve as the PI lead for this year (one-year term), Dr. McClain to serve a two-year term, and Dr. Disis to serve a three-year term. The Committee also decided to hold a review of Consortium projects that are aligned to SGC 5 at its next meeting in May.
- Also at the April 30 meeting, Dr. George O'Connor, of Boston University, presented a draft proposal for collaborative translational pilot grants involving multiple CTSA institutions. The basic premise of the proposal is to encourage CTSA institutions with similar interests to come together on project ideas, allowing for each CTSA to use its funds only for the portion that would take place within its own institutions. The SGC participants are currently reviewing this proposal and will provide feedback to Dr. O'Connor before he submits the proposal to the CCSC.
- The Committee also learned of the Collaboration pages on CTSAWeb.org (<http://www.ctsaweb.org/index.cfm?fuseaction=quicklink.showCollabOpps>), and discussed the possibility of having a meeting immediately prior to the October CCSC face-to-face meeting. The Committee is tentatively aiming for October 5.

**Meetings Planned:**

- The SGC meets on the third Monday of each month from 3:00 – 5:00 pm, Eastern. The meetings for the next three months are as follows:

- May 17, 2010
- June 21, 2010
- July 19, 2010

### **CTSA Consortium Child Health Oversight Committee (CC-CHOC)**

PI Liaison(s): Lisa Guay-Woodford, Jim Heubi, Ron Sokol

Chair/Chair-elect: Shari Barkin/William Smoyer

NIH Coordinators: Mary Purucker (NCRR), Steven Hirschfeld (NICHD)

Booz Allen Hamilton Project Manager: Ashley Harris

**Full CC-CHOC:** Includes members from 45 of 46 CTSA's plus NIH staff, similar to CCSC in size. Full CC-CHOC holds quarterly webinars (last on 02/11/2010) and yearly face-to-face (last on 04/30/2010).

**Operations Group (OG):** Nine members (includes two NIH), conducts most day-to-day business of the CC-CHOC. Operations Group meets via teleconference monthly (last on 04/21/2010).

There are six CC-CHOC Workgroups, one taskforce (Core Competencies) and two liaisons (CER KFC). The Rare Disease workgroup is administratively tied to the CC-CHOC but is a CTSA consortium-wide group. Other workgroups are Metrics of Success, Pediatric Research Ethics (PREW), Pediatric Drugs and Devices, T2 Research, and Lifespan.

#### **Activity Updates (by Meeting date and Workgroup):**

- **(Full CC-CHOC)** Annual face-to-face meeting was held April 30 in Vancouver immediately prior to and in conjunction with the Pediatric Academic Societies meeting. The final agenda is posted on the wiki and [ctsaweb.org](http://ctsaweb.org). A meeting [wiki](#) page has been created and holds meeting materials and speaker's final PowerPoint presentations. The face-to-face meeting generated a list of priorities and deliverables for the upcoming year that the CC-CHOC OG group will be discussing and refining during the next call on Wednesday, May 19.
- Both **CC-CHOC** activities supported by a successful 3-year R13 grant to Vanderbilt (Barkin)
  - The **Metrics of Success** Pilot has received data from 37 institutions. Sites may (confidentially) self-enter data into a customized REDCap database developed and maintained by the Vanderbilt CTSA. Results were discussed by the workgroup and presented during the April 30 face-to-face meeting.
  - Lead by Dr. Steven Hirschfeld, the **PREW** continues its efforts to establish a federated, facilitated IRB review process for multisite pediatric studies, most recently in partnership with the NCS. Several BPCA Outcome studies have signed on as participants in the pilot currently underway. The PREW coordinates its activities with the CREW on a regular basis through shared membership and regular updates.
  - The co-chairs of the **Pediatric T2 workgroup** attended the April 23 meeting of the Community Engagement KFC to further collaboration.

- The former co-chair of the **Pediatric Drugs and Devices** workgroup, Dr. Carole Marcus, is completing her survey of the scientific review practices currently in place at CTSA institutions. Preliminary data show that most CTSA sites still use a Scientific Review Committee to review protocols at their site, suggesting that a coordinated, multi-site scientific review process might help to reduce the start-up time for multisite clinical studies. The results were discussed at the April 30 face-to-face meeting.
- The new co-chairs convene the **Pediatric Drugs and Devices workgroup** during the upcoming CC-CHOC face-to-face meeting for strategic planning session and to discuss the agenda for an upcoming workshop to be held in September 2010.
- An Excel spreadsheet depicting overlap between the current Key Function Committees (KFC) and each CC-CHOC Workgroup or Taskforce was discussed at the April 30 face-to-face meeting. The proposal will assign each CC-CHOC workgroup the responsibility of following the activities of a specific KFC and with providing the child health perspective to that KFC. It is hoped this process will make KFC-CC-CHOC interactions more robust and to ensure more consistent and predictable communication will occur.
- The Pediatric Clinical and Translational Investigator **Core Competencies** Taskforce, composed of CC-CHOC participants, reviewed the 14 core competencies developed by the Education and Career Development KFC to ensure the child health perspective is represented. The taskforce is in the process of developing recommendations for additions to the competencies.

**Meetings Planned:** CC-CHOC meets quarterly. The next meeting is currently being scheduled for August 25, 2010 at 10:30 AM ET.