HIV/AIDS Network Coordination Quarterly Report
Q2 2007: September 1, 2007 – November 30, 2007
Submitted December 17, 2007

This quarterly report covers cross-network coordination objectives and activities carried out by the cross-network committees and working groups and the HIV/AIDS Network Coordination Office during the period of September 1, 2007 – November 30, 2007. The HANC office works under a contract agreement between the Division of AIDS of the National Institute of Infectious Diseases (DAIDS) and the Fred Hutchinson Cancer Research Center. The programmatic lead for HANC activities is Dr. James Kublin. The HANC mission is to support the science and operations of the DAIDS-funded global HIV/AIDS clinical trials networks by increasing efficiency and resource-sharing through cross-network coordination of critical activities.

HANC SUPPORT ACROSS ALL COORDINATION AREAS

HANC Web Portal

The HANC office is developing a collaborative environment and resource with a focus on information and knowledge management. Although we understand that adopting a new technology can be challenging, the tools we are developing support the sharing of information critical to the efficient conduct of clinical trials. Our focus is to assist with the development and implementation of various tools and technologies that increase the level of coordination and reduce the barriers to efficient research. A critical component of the HANC effort is directed toward the ongoing development, testing, and implementation of various tools on the HANC Web Portal.

The HANC Web Portal currently includes a document management area; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; and a cross-network directory. 335 individuals currently have active HANC Portal user accounts. Eighteen secure team sites have been established for specific cross-network committees and working groups and are being used for collective document development, online discussion, and sharing of documents and information. Custom tools have been developed to meet specific needs identified by the training and laboratory cross-network groups.

Although currently only a small number of the hundreds of HANC members are using the portal on a daily or even weekly basis, this number is increasing along with the utility of the portal. A selection of the many projects currently underway to support these activities is provided below:

- Development of web services that will make the DAIDS-ES Master Contact system accessible to HANC Portal users. This tool was built during the second quarter and is currently in testing with an anticipated release date in early 2008.
- Development, implementation and further revision of a Training Request mechanism for capturing and tracking cross-network training requests.
- Support and optimization of the Proficiency Testing Tracking tool and site which captures laboratory proficiency testing data and manages work flows so that appropriate contacts are notified of proficiency testing failures, feedback is collected and sites can be notified in a single communication of multiple network responses.
- Training and support for the ACTG/IMPAACT Lab Tech Committee's utilization of the HANC Portal's document management functionality for collaborative editing and updating of their laboratory manual.

Requests to Access the Clinical Research Support (CRS) Contract

The CRS contract between DAIDS and PPD can be accessed by the Networks to fund a variety of clinical research support tasks. Requests for CRS services that apply across Networks are made through the HANC office. Fifteen cross-Network CRS requests have been submitted since the CRS contract was initiated. Since September 2007, HANC staff submitted one new CRS request for support to hold monthly cross-network grand rounds via teleconference to present and discuss treatment, prevention and vaccine cases. The virtual grand rounds are intended to provide those involved in safety across the networks including physicians and nursing staff at clinical sites with an excellent learning opportunity and discussion forum on complex cases. The Risk Reduction Counseling activity supported through a CRS request submitted in the previous quarter was kicked off in October and is described in further detail in the Training section. Networks were able to begin accessing the "HANC agreement" for reduced pricing of costly genotyping kits in November at a 29% discount for Abbott Viroseq and16-29% discount for components of the Siemens Trugene, which resulted from a CRS request submitted back in March 2007. Details of these CRS requests can be viewed from a link on the HANC Portal homepage, which also contains an online CRS request submission form.

SPECIFIC AREAS OF CROSS-NETWORK COORDINATION

The HANC office currently facilitates cross-network coordination activities related to Scientific Leadership, Laboratories, Logistics and Training, Community Participation and Education, Statistics and Data Management, and Performance Evaluation.

Network Leadership and Oversight of Coordination Activity

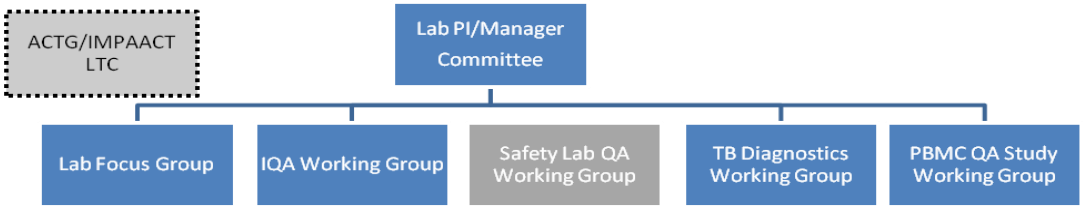
The AIDS Clinical Trials Network Leadership Operations Group (NLOG) and the AIDS Clinical Trials Network Strategic Working Group (SWG) are cross-network bodies established by DAIDS that the HANC office participates in and helps support. The NLOG is charged with implementing and advancing optimal collaborative clinical trials research activities among the NIH-sponsored HIV/AIDS clinical trials networks. This group considers crucial operational and scientific questions to drive collaborative efforts among the networks and other research partners and oversees the coordination of common activities across the networks. The NLOG makes recommendations to NIAID and DAIDS regarding resource allocation that would improve efficiency within and across networks. Since 2006 HANC has facilitated monthly teleconferences for the AIDS Clinical Trials Network Leadership Operations Group (NLOG) to consider Leadership-level coordination issues and provide oversight to the overall coordination activity. One NLOG call in has been held this quarter. The November 2007 call included a presentation and discussion around cross-network laboratory coordination.

The AIDS Clinical Trials Network Strategic Working Group (SWG), facilitated by DAIDS, is a working group of ARAC that is intended to provide strategic review and planning for the coordinated research efforts of the NIAID-funded HIV/AIDS clinical trials networks. The SWG provides input on strategic issues that cut across all six HIV/AIDS clinical trials networks, including overall priority setting for research plans, assessment of research opportunities and coordinated strategic planning across the networks. The working group is convened periodically to review and discuss cross-network issues as well as specific scientific plans, progress and opportunities. The SWG held its third meeting November 1-2, 2007 in Washington D.C. This meeting focused an overview of the President's Emergency Plan for AIDS Relief activities, an update on the IMPAACT network scientific agenda, the HPTN domestic prevention research agenda, HPTN 060 protocol proposal, and continued discussion of acute infections.

HANC also facilitated 3 focused monthly conference calls this quarter with the six Network Principle Investigators to address cross-cutting network leadership issues.

Laboratory Coordination Objectives and Activities

HANC currently supports seven cross-network laboratory groups. Five of these groups are actively working on specific laboratory coordination objectives outlined in the workplan – this includes the Lab PI/Manager Committee, the Lab Focus Group, the Immunology Quality Assurance Working Group, the TB Diagnostics Working Group, and the PBMC QA Study Working Group.



The Lab PI/Manager Committee provides oversight and direction to identify and address laboratory training, operations, and support issues that apply across Networks. They regularly review progress and discuss issues raised by topic-specific working groups.

HANC provides technical support to the ACTG/IMPAACT Lab Tech Committee by providing a team site on the HANC Portal where the group is coordinating their activities and utilizing the HANC Portal's document management functionality for collaborative editing and updating of their laboratory manual.

The Lab Focus Group (LFG) has continued to meet 2-4 times per month via teleconference to address on an accelerated timeline issues such as the development of communication plans for proficiency testing with external QA partners. They have continued to utilize a web-based PT Tracking tool to provide sites with a single summary of the network responses to a PT failure. A cross-network communications plan for safety PT problems was implemented August 1 and used as a model for the development in collaboration with the VQA of a similar plan for virology PT problems. The VQA plan is under review at this time with the intent to finalize and implement in early 2008. During this quarter the LFG has also developed a comprehensive consensus HIV testing algorithm, the draft of which will be provided to DAIDS for review in early 2008.

The Immunology Quality Assurance (IQA) working group has used monthly IQA teleconferences as a forum to discuss and determine how best to address CD4 proficiency testing issues identified by the IQA and UKNEQAS at international labs. They have clarified performance guidelines and the process for enrolling/discontinuing Network non-US CD4 labs in the UKNEQAS program and are exploring centralized shipping for labs in Brazil to resolve QA panel shipping challenges.

The Safety Lab QA Working Group activity has been suspended during this quarter while the Lab Focus Group and SMILE directly address the coordination and communication of proficiency testing for safety labs.

A TB Diagnostics working group including SMILE, CDC, ACTG and HANC members was first convened in March 2007 to discuss and address questions regarding TB diagnosis that came up related to ACTG protocol A5221. The group collected TB laboratory information from A5221 international sites and queried sites about their TB diagnostic QA procedures and willingness for a SMILE site. A small number of international sites were identified for SMILE visits to conduct hands-on assessment of their TB Diagnostic capacity and quality. The first site visit to Fiocruz, Brazil was completed in this quarter and on 11/6 the group reviewed the SMILE report. SMILE felt that FIOCRUZ could be a TB diagnostic teaching site in Brazil, but there were a number of recommended changes to help them improve their TB processing. An action plan detailing these recommendations was sent to the lab. SMILE site visits also took place November 24-December 9 for the NHLS lab in Johannesburg, the Durban lab and the Blantyre and Lilongwe labs. The group will reconvene via conference call in late January to review the reports from these sites visits;

discuss what the next steps will be once a lab is "established;" and pursue a more coordinated international approach to TB diagnostics and proficiency testing.

An ad hoc working group was formed in September to design a study for the Optimization of Storage and Transportation of Cryopreserved PBMC. This group is chaired by Adriana Weinberg from the University of Colorado with support from HANC. They have drafted a study design that is currently under review. Five labs have agreed to participate in the study (HVTN, University of Massachusetts, University of Colorado, Duke-CHAVI and University of Miami).

During this quarter the following progress was made in support of major laboratory objectives:

Laboratory Objective 1: Maintain a structure and processes for consistent communication and access to critical information across the Network Core Laboratory Programs.

- Network Lab PIs, Network Lab Managers and DAIDS Clinical Laboratory Oversight Team (DCLOT) members convene on a monthly Lab PI/Manager teleconference to identify and address laboratory training, operations, and support issues that apply across Networks, and review progress and discuss issues raised by topic-specific working groups.
- A decision was made to postpone an annual face-to-face meeting of Laboratory PIs, Laboratory Managers, DAIDS Laboratory program staff, and key contractors/partners until spring 2008 to coincide with joint Network meetings. Planning for this meeting will begin in January 2008.
- Laboratory coordination team sites on the HANC Portal are being utilized by the working groups for communication and review and tracking of laboratory issues such as proficiency testing results and associated corrective action. The ACTG/IMPAACT Lab Tech Committee has been provided with a team site in which they are using the HANC Portal document management tools to collaboratively review and revise their joint Laboratory Manual in an efficient and transparent manner.
- A lab database on the HANC Portal contains information on bar-coding equipment, laboratory staff contacts, affiliated Networks, and location. HANC has initiated discussions regarding integrating the database with the DAIDS-ES Master Contact System and as a longer-term solution possibly expanding the DAIDS-ES Master Contact System to include these additional parameters useful to the Network Core Laboratories, such as an inventory of laboratory equipment, local reference ranges for specific analytes, assays conducted, and access to operating procedures.

Laboratory Objective 2: Establish standard quality assurance across networks and other partners through the further development and implementation of a Total Quality Management Program.

- The Total Quality Management plan proposed in late 2006 included the formation and facilitation of Quality Assurance Working Groups for each of the areas of laboratory quality assurance that involve the networks.

    1. Immunology Quality Assurance (IQA) working group teleconferences were held in September and October for the IQA working group to discuss and determine how best to address CD4 proficiency testing issues identified by the IQA and UKNEQAS at international labs. Performance guidelines have been developed and the process for enrolling/discontinuing Network non-US CD4 labs in the UKNEQAS program has been clarified.
    2. The Safety Lab QA working group calls were suspended while the Lab Focus Group worked with SMILE to address safety lab proficiency testing communication issues. In consultation SMILE and the LFG developed a cross network communications plan for safety PT problems and failures which was implemented in August 2007.
    3. Work began this quarter with the Virology Quality Assurance group to develop a cross-network communications plan for virology PT problems.

4. A call was held on 10/9 to determine what the networks agree is necessary to include in a validation plan for VQA viral loads and come to consensus around a common process that will apply to all networks. As new assays come on board and replace previous assays on protocols it will be critical to have standardized validation plans agreed upon in advance. The intent of this effort is to pilot a validation plan in early 2008 and have the Lab PI/Mgr group review the data after the pilot is completed.

- The Lab Focus Group continued to utilize the web-based cross-network PT Deficiency Response tool which allows the Networks to coordinate their responses and provide sites with a single summary of the network responses to a PT failure. The intent is to support timely coordinated responses to potential problems, transparent tracking of issue resolution, and the ability to track and respond to trends over time.

Laboratory Objective 3: Harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.

- HANC staff worked with PPD and FSTRF to collect data on training provided to site lab staff which will be made available in a cross-network database so that the Networks can be aware of training needs. This database is also intended to assist the PNLs in tracking the distribution of IATA training CDs and alert them when IATA training updates are needed.
- The consensus PBMC processing SOP developed by the Networks and HANC was reviewed in a comparative study to determine if there are critical differences between the consensus SOP and that used by external partners such as CHAVI for specific procedures involved. The data from this comparative study was shared in a poster session at the CHAVI annual meeting and will be made available to the Networks pending publication in December 2007. Next steps for implementing the consensus SOP will be pursued in early 2008.
- Work with the Cross-Network SDMC Committee on LIMS-LDMS issues such as standardizing common data items used to identify specimens across networks was postponed until the third quarter due to other data management issues taking higher priority.

Community Coordination Objectives and Activities

Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the DAIDS-sponsored HIV/AIDS Clinical Trials networks conduct research. CP will harmonize community-related practices within the networks as well as with external stakeholders to facilitate coordination of community-based activities. The HANC Community Partners Project Coordinator serves as a non-voting member of CP and provides group facilitation, project coordination, fiscal oversight, and administrative support.

Community Partners Objective #1: Develop and implement Community Partners membership and operations. Strategies and activities undertaken during this quarter to support this objective include:

- Community Partners Executive Committee and NLOG/SWG Representatives were selected as part of the leadership structure of the group.
- A Nominations Working Group was formed to assist in identifying nominees for the CP Co-Chair positions. A member survey was conducted to determine general interests and leadership potential within the group, followed by a series of telephone interviews.
- *Develop CP member internal communications through improved access to interactive online tools.*
    - HANC continued to provide technical assistance to address portal and team site access issues. Group and individual training on the portal was provided periodically, including a live portal demonstration/presentation at joint meeting with two of the Networks.

- By request of the membership, user permissions for Community Partners, Community Training Working Group, and Community Recommendations Working Group were changed to allow each of these groups read only access to each other's team sites.
- Quarterly reports on working group activities were arranged to be given on the CP calls by appointed liaisons to allow for better and more consistent information flow between the working groups and CP.

- *Develop relationships within cross-network leadership groups and increase awareness of CP within relevant community groups.*
  - CP selected two representatives to participate on the NLOG and SWG. The new reps attended the November SWG meeting and provided a report to CP. A letter of introduction was sent to the NLOG members. The letter included a summary of qualifications and backgrounds of the two new reps.
  - CP Executive Committee discussed the best process for providing feedback to the reps to assist them in effectively assessing and presenting a cross-network community perspective on SWG agenda items.
- *Identify CP activities that best support the mission and vision of the group.*
  - CP completed its Y2 work plan in October 2007 through a process that included direct feedback from all its working groups. The work plan directly informed projected expenses for the CP Y2 budget, which was completed in November.
- There were two additional and unexpected opportunities that CP was involved with in this quarter:
  - Open Letter on Sex and Gender- A group of Washington DC community advisory board members developed a letter requesting an examination of the way that sex and gender data is collected across the DAIDS Networks. The letter also called for greater sensitivity from research staff towards the transgender population and consideration of inclusion of transgender participants in HIV clinical trials research. The group approached CP for their support of the letter. CP discussed the letter and explored questions regarding the international perspectives on the issue and how data is currently being collected. CP formed an ad hoc working group to continue to examine the issue. Members of this working group met with DC area CAB members to further discuss the letter. The CP ad hoc working group hopes to work with a cross-Network Data Management Center (DMC) group starting in January 2008 to explore the question of data collection standardization in this regard.
  - Response to call for public comment on "Issuance of a Visa and Authorization Admission into the United States for Certain Nonimmigrant Aliens Infected with HIV"- The US Department of Homeland Security, Bureau of Customs and Border Protection, Border Security Regulations Branch called for public comment regarding the current US policy which limits persons living with HIV from travelling into the country. Comments were requested in order to determine whether a change to this policy should be considered. Community Partners members drafted an educational letter which detailed how this policy currently impacts international community member participation in network meetings and conferences.

Community Partners Objective #2: Develop recommendations on providing community input into the planning and implementation of research activities. Strategies and activities undertaken during this quarter to support this objective:

- *Complete community recommendations document and references.*

- The Community Recommendations working group (CRWG) members completed drafts of the 6 main sections of the recommendations document, as well as introductory statements, at the end of November.
- A table format for each section was developed in order to more easily present specific roles and responsibilities of community representatives, research team staff, Network level community representatives, Community Partners and DAIDS.
- Case narratives from each Network were collected and an introductory statement to the narratives was drafted.

- *Involve community in review process of document*. As part of the CP work plan discussions, CRWG members identified a timeline for completion of the first draft of the recommendations document.
  - The group developed a plan for community review of the document, and began identifying key stakeholders to include in the review process.

Community Partners Objective #3: Utilize the Community Training Working Group to coordinate and develop cross-network CAB training materials. Strategies and activities undertaken during this quarter to support this objective:

- *Develop CAB training materials that are relevant across the six DAIDS-funded HIV/AIDS clinical trials networks.* A document review tool was developed to help Community Training working group members in their review of existing community training modules from several networks. The group began reviewing modules from one of the Networks, to assess how easily the training materials could be adapted for cross-Network use.
- *Distribute CAB training materials to relevant network staff and community groups.* As part of the document review process, the group began identifying which training materials it would recommend be shared within a cross-network library. Once an initial list of documents to share has been identified, the online public library resource will be developed.

Community Partners Objective #4: Identify, articulate and communicate scientific priorities of communities that are developed within the network community groups, areas of divergence from scientific researchers' priorities, and unaddressed issues or unmet community needs. Strategies and activities undertaken during this quarter to support this objective:

- *Develop scientific priorities that reflect community needs and interests within the networks.* CP chose to create of a Scientific Priorities Steering Committee in order to begin the development of cross-network community scientific priorities. An initial call for the committee is expected in January 2008.
- *Develop methods and processes for ongoing communication of scientific priorities to network leadership groups and researchers.* Initial discussions were begun on the December CP Executive Committee call regarding the ideal process for ongoing communications with NLOG/SWG. The group expects to further develop these processes as part of the organizational guidelines review, planned to take place in the spring of 2008.
  - CP began plans for a face to face meeting in spring 2008, which will focus on articulating cross-network community scientific priorities, along with other organizational and working group discussions.

Training Coordination Objectives and Activities

Training coordination includes compiling and sharing the vast library of training materials already developed within networks, identifying common Core Competencies, and collaborating on the development of new standardized training modules that are applicable across networks. The following working groups were put in place by the Cross-Network Training Committee to actively develop specific cross-network training: Safety and EAE Working Group, Admin-Fiscal Working Group and (in conjunction with Community

Partners) the Community Training Working Group. The Cross-Network Training Committee continues to identify high priority areas that will address network and Clinical Trial Unit (CTU) training needs. An additional working group, the HIV Research Counseling and Testing working group (formerly known as the Risk Reduction Counseling working group) became active in September 2007.

Training Objective #1: Develop and enhance common safety training modules. Strategies and activities underway in the second quarter to support this objective:

- The Safety and EAE working group continues to focus on safety evaluation and reporting including broadening safety assessment training with a focus on EAE, attribution and case studies. Working group members and several of the DAIDS Medical Officers continued discussing the different training methods and safety-related topics during their monthly calls and via email.
- A standardized online and CD-ROM EAE training module is still in development. These materials are being produced under a separate contract under the RAB/RCC office.
- A generic Attribution Training module has been developed and was presented at DAIDS Regional Training Events held in Lusaka, Zambia and Miami, USA. The feedback from the training sessions was positive and network staff have voiced great interest in the training. The working group is now discussing how to best disseminate the training so sites can use the training in-network. Providing CE credits for Attribution training is still being researched.
- The CRS task request for the Safety Grand Rounds continues to be under review is has not received final approval. In anticipation, however, a draft invitation letter and participant flier has been developed and is under review by the working group.

Training Objective #2: Develop a modular fiscal and administrative training program to help research administrators meet minimum NIH standards. The Cross-Network Admin-Fiscal Training Working Group was tasked in 2006 with developing an administrative & fiscal training program for CTU staff to meet minimum NIH standards. The working group developed an administrative and fiscal specific training Needs Assessment and CRS contract funding was obtained for distribution and compilation of data into a report. The Admin-Fiscal working group met face-to-face May 2-3, 2006 to review the data, prioritize training needs identified in the report, and plan for curricula development. Strategies and activities underway in the second quarter to support this objective:

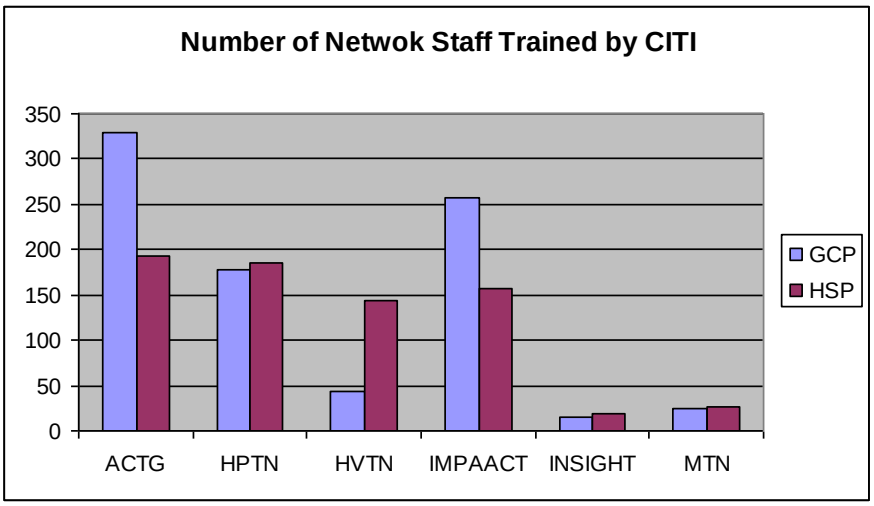
- At the beginning of this quarter leadership was informed that the training module development activity by the Admin-Fiscal working group has been placed on hold at the request of the Office of International Extramural Activities, Division of Extramural Activities (DEA), NIAID, NIH, DHHS. Upon coordination of their upcoming Grants Policy Management workshops, the DEA reviewed the materials from Admin-Fiscal Training WG and found considerable overlap between their training efforts and those of the working group. As a result they asked that the activities of the Admin-Fiscal Training WG be suspended.
- The OIEA held two 3-day workshops in Peru and South Africa on Grants Policy and Management Training, which were attended by staff affiliated with research sites working with many of our networks.
- A letter was submitted to the Director of OPCRO asking for assistance in facilitating a discussion between the Network PI's and the OIEA to make sure an Admin-Fiscal program will be adequately sustained given that periodic regional training workshops may not provide the knowledge base that an on-demand administrative and fiscal training program was intended to do. Discussion has been held between HANC, DAIDS and OIEA and comparison of the two efforts is intended to take place in early 2008 to identify where any overlap actually exists and determine how to move forward with the efforts that are not duplicative.

Training Objective #3: Develop a centralized communication process for scheduled domestic and regional trainings and managing training requests. Strategies and activities underway in the second quarter to support this objective:

- The Training Committee is working with DAIDS to strategically plan future DAIDS Regional Training Events to coincide with other meetings and/or events in hopes of capitalizing on staff attendance.
- A discussion has begun among the Training Committee members of how to best share in-network training activities that may be applicable to pluripotent sites.

Training Objective #4: Develop and provide access to cross-network standardized training for high priority topics including risk reduction counseling, research methodology, Good Clinical Practice (GCP) and Human Subjects Protection (HSP). At a December 2006 meeting, the cross-network Training Committee identified a number of high priority topic areas for additional coordinated training development. Strategies and activities underway in the second quarter to support this objective:

1. Risk Reduction Counseling (RRC) training development:
   - An initial kick-off planning meeting took place in mid-September with members of the Executive working group to prepare for the full Risk Reduction Counseling working group kick-off meeting.
   - An RFP was prepared and released for vendors to create a DVD e-learning training for staff. A final vendor should be identified by mid-December 2007.
   - Twelve sites (6 from Latin America and 6 from South Africa) were invited to participate in a pilot program to evaluate the new training materials in development over the course of the year. Prior to the F2F meeting, staff involved in RRC were identified by their site PI to take part in an on-line survey regarding RRC. Two on-line surveys were disseminated in October, one in English and sent to the SA sites and one was translated into Spanish via a HANC office contractor and sent to the Latin America sites. Approximately 90% of staff identified participated in the survey prior to the kick-off meeting where preliminary data would be reviewed. All 12 sites are represented in the data compiled.
   - A 3-day F2F kick-off meeting was held October 29th-October 31st in San Francisco. Preliminary training materials (a pre-training packet, self-directed learning packet, a pre and post training quiz and possible vignettes) were reviewed over the course of the meeting. The group officially changed the working group name to the HIV Research Counseling and Testing working group highlighting that this counseling is geared towards clinical research sites.
   - The working group has set-up bi-weekly calls to move the work of this group forward quickly. The Executive working group will meet monthly to be sure the task stays on track and within budget.
2. Research Methodology training development:
   - Several training modules were already available and are provided in the cross-network training inventory. Additional resources, such as websites and articles have also been compiled. These resources have not been further discussed but will be revisited by the Training Committee in the third quarter if further action is needed.
3. Good Clinical Practice (GCP) and Human Subjects Protection (HSP) online training module development and access:
   - HANC continues to work with the CITI on-line course program to improve their site access and module development for GCP and HSP. To date, over 1500 certificates have been awarded via this training mechanism, and the following figure illustrates the number of staff by network who have become certified:



- Spanish translation for the GCP curriculum has been completed and is under voluntary review by site staff who are native Spanish speakers. The availability of the Spanish GCP curriculum will be announced in December.

Training Objective #5: Develop a long-term plan for implementing standardized training across the networks. Strategies and activities underway in the second quarter to support this objective:

- Two learning community meetings have taken place. The first occurred in Lusaka, Zambia at the end of September and the second discussion took place in Miami, Florida at the end of October. Site staff from each region where the meeting was held were invited to attend and many participated. Cross-network Training committee members that were available dialed into each discussion. Some of the questions asked of staff that attended included what types of trainings are most needed, what are some of the barriers that staff face to become trained, what would be some ways to select trainers and incentives to keep trainers involved? One approach discussed in developing this community would be to build this program at different levels and have the resources available at each level for staff to access. Resources available to start with are the DAIDS Learning Management System, training inventory, and needs assessments networks have gathered for their sites. DAIDS is putting together a final report of the discussion that took place and will distribute appropriately so all can provide input. DAIDS will work closely with the networks on how to best deliver the training locally and provide a platform all networks can build on.

- The Training Committee will continue to review best practices in training and is looking to gather data that will evaluate staff knowledge of training opportunities, uptake of training and satisfaction with training outcomes. This data will be considered along with resource availability and identified training needs in specific areas will assist us in guiding planning for a long-term training program.

Site Management & Clinical Trials Logistics Coordination Objectives and Activities

Site management and oversight, harmonization of clinical trial logistics and operations at the site level across the networks has been identified as an area of potential high priority for coordination in the second year of the grant period. Although this is an area of coordination with great potential for harmonization, HANC has not yet convened a working group to identify objectives, nor have we initiated any substantial site management & clinical trials logistics activities, in part because DAIDS is still in the process of developing an Office of Clinical Site Oversight (OCSO) and any cross-network activities in this area will need to be undertaken in close collaboration with this nascent unit.

On October 31 HANC staff met with OCSO and OPCO staff to share information about cross-network activities currently underway; determine OPCRO/OCSO receptivity to the proposal in the HANC work plan to convene a cross-network Site Management and Clinical Trials Logistics working group for the purpose of identifying and prioritizing site management issues that should be addressed collaboratively by DAIDS, HANC and the Networks; present a limited list of issues identified that need a collaborative approach for resolution; and agree on next steps for putting communications tools and processes in place to work together. Among the next steps identified at the meeting were:

- Clarification of which online resources to access for what purposes. To address concern that site staff don't know where to go (PPD, RCC, DAIDS, NIAID, Network websites?) to find the information they need, HANC will provide clarification and cross-linkages on the public and private sites of the HANC portal to direct staff regarding where to go for what information.
- Develop a collaboration space where HANC and OPCRO/OCSO staff can share information and begin to collaborate. HANC will set up a team site on the HANC Portal for HANC and DAIDS to post and address these issues. Timeline: Team site made available to OPCRO/OCSO staff in January 2008.
- Revise data module. HANC will work with the DMC Harmonization Working Group to revise the data module. HANC will share the revised module with Maureen and Karen when it is complete. Timeline: January 2008.
- Take next steps to address the Site Management and Clinical Trials Logistics objectives in the HANC work plan. HANC will put together an outline for convening a working group, addressing roles and responsibilities, and identifying high priority issues to address and share this outline with OPCRO/OCSO for discussion. Timeline: January/February 2008.

In 2008 as OCSO is better established and functioning, HANC will be working with them to pursue the initial exploratory objectives listed below and described in detail in the HANC Strategic Work Plan.

- Site Management & Clinical Trials Logistics Objective #1: Develop a Cross-Network Committee focused on Site Management and Clinical Trials Logistics Coordination.
- Site Management & Clinical Trials Logistics Objective #2: Identify and prioritize coordination objectives and activities to pursue that will add value for the networks, sites and DAIDS.

HANC is also collaborating with the Admin/Fiscal leadership across the networks to develop common cross-network protocol costing templates. This is not intended necessarily to mandate one template for all protocols, but to identify areas/modules that can be applied to cost specific activities. To initiate this effort, HANC has:

- Collected and reviewed elements of costing out protocols and current methodology/templates that the networks use for proposing site and core costs.
- Developed a short-term plan with the Networks for future activity.

SDMC Coordination Objectives and Activities

The network Statistical and Data Management Centers (SDMCs) have identified key areas in which the sharing of expertise, resources, and procedures will strengthen the capacity and increase the efficiency of SDMC operations. A DMC Harmonization Committee has been established to address the objectives outlined in the HANC work plan. In the second quarter of this year the DMC committee convened 2 full-group conference calls and held additional small-group meetings to make progress on the Establishment of an IT Best Practice Document and Process for Implementation; determining how to move forward with the DAIDS Data Collection Site Module; addressing questions from other DAIDS-funded collaborators regarding

Non-AIDS defined Events and Sex/Gender data capture processes; and establishing a format for SDMC calls that will allow a wider-forum of discussion.

Information Technology Best Practice Standards at Division of AIDS Clinical Trials Study Sites and Affiliated Laboratories

As DAIDS network sites and laboratories often receive funding from multiple sources, it is common for sites to share their infrastructure (including data-acquisition devices) for different studies across different networks. In spite of the commonality of multi-network utilization, there are currently no common strategies for establishing a technological standard at sites, or insuring that changes made to a site's technical infrastructure by one network won't negatively impact the work being done by another. The DMC Committee has agreed on the importance of developing a mechanism that: reviews the current IT Infrastructure at each site; identifies the optimal standards achievable for that site given its location and financial and personnel resources available; communicates recommended improvements to all networks affiliated with that site; and implements necessary improvements in a way that does not “break” essential systems at any networks involved.

- In the previous quarter, HANC and the SDMCs worked to establish a set of baseline technological standards (specifying both the minimum and ideal requirements) for sites and laboratories, both domestic and international, in the following categories: Power Stability/Reliability; Anti-virus/Spyware protection; Data and telecommunications; Local-Area Network; Centralized File and Applications Server; Data Backup/Recovery and Disaster Recovery Plan; Security; and IT Training, Documentation and SOPs/WPGs. These standards were documented in an “IT Best Practice Standards” document that was drafted, reviewed, discussed, and finalized by representatives from SCHARP, FSTRF, and CHAVI. The final IT Best Practice Standards document was shared with DAIDS leadership as a documentation of IT recommendations to be considered for all DAIDS-funded sites and affiliated laboratories. The feedback from DAIDS was positive; however it has been made clear that they do not assume responsibility for resources needed to assure all sites are up to optimal standards. Further discussions will determine how these efforts will be resourced.
- Following the finalization of the IT Best Practice Standards document, the SDMCs continued discussions to identify the appropriate representatives from the network SDMCs, CHAVI, DAIDS, and any other relevant partners that should make up the oversight body that will monitor and regulate the IT standards outlined in the document. In addition, discussions around establishing the process for a coordinated channel of communication surrounding technological issues among this oversight body have continued. This process has included: identifying which changes to IT structure at sites/labs require review and comment by the oversight committee; identify the best communication tool to propose/share IT changes that might be relevant across networks and knowledge areas; identify the best way to document these discussions and outcomes in order to compile an IT history for each site/lab. HANC anticipates this processed to be defined by the end of the third quarter, with the process implemented by the end of the fourth quarter.

DAIDS Data Collection Site Module Discussions

- The DAIDS Data Collection Site Module that was assumed to have been distributed and completed by DAIDS-funded sites was actually not distributed or completed. Given that this data is essential for optimal Data Management infrastructure planning and management, the DMC Committee decided to work to ensure the questionnaire is completed for all DAIDS-funded sites. In addition, the DMC will be working to review and make recommendations for additions/changes to the module before it is distributed so that the module could be used to replace multiple questionnaires that are given to sites from each Network. The HANC office and the SDMC will be working in the third quarter on finalizing this Data Collection Module and determining how, when, and by whom it will be distributed and data collected and made available.

Non-AIDS Event Definitions Discussions

- This past quarter the HANC office was queried by investigators and project officers at DAIDS with regards to how the non-AIDS event definitions are reported and coded. Up until now, in the "When To Treat" protocols discussion has taken place about looking at the AIDS defining events as a critical endpoint. However, there are other events that are non-AIDS defining according to the traditional WHO/CDC criteria that are associated with HIV infection and these are the events that need to be identified and harmonized. Initial discussions with the DMCs about these efforts showed that there has been significant effort toward MedRA coding harmonization between the DMCs because if they are coded correctly and using the MedRA procedures then that would probably provide at least the initial level of harmonization that's required. The next level would be looking at what are those non-AIDS events that people are interested in among HIV infected individuals. HANC gathered initial information from each of the DMCs about how their respective centers handle the coding and capture of these events. Given the initial information collected, it was decided that this issue requires further in-depth discussions to ensure there is harmonization in this area. Following these discussions within the DMC committee, the HANC office will compile a brief summary of these results and have a more extensive discussion with the project officers at DAIDS and others who are interested in these activities in the coming quarter.

Sex/Gender Data Collection Discussions

- This quarter the DMC Harmonization Committee was asked to discuss and advise on the current discussions regarding sex and gender data collection at trial sites. This request came from Community Partners, the cross-Network community representative group for the DAIDS HIV Clinical Research Trials Networks, who were asked to support a letter from Washington DC area community advisory boards that calls for an evaluation of the way sex and gender data are collected within trials, as well as greater sensitivity and staff training for working with and recruiting transgender trial participants. Community Partners needed the following information to be better informed on the issue:
    1. How is data on sex and gender (or transgender identity) currently captured within the DAIDS Networks?
    2. What recommendations to data forms or other measurements might be suggested to best address inclusion of transgender trial participants?
    3. How might this data collection differ inside and outside the U.S. and for different types of trials? How might this impact data collection across the Networks?

- Research by each of the DMCs determined that there is no systematic collection of transgender data among the protocols supported by either of the DMCs, unless it is specifically part of the protocol objective. In the coming quarter, the SDMC committee and HANC will come up with a set of definitions that will be requested to be included in 1-2 protocols in each network as a pilot. From there, it will be determined whether it should be required that additional questions be included in the registration system/CRF process. The SDMC will work actively with the Community Partners group on these efforts.

Improved Communication and Coordination between DMCs

- In addition to the monthly calls to move the SDMC group towards meeting the objectives in the yearly work plan, a need has been identified for the DMCs to specifically discuss the IT infrastructure on a monthly basis- what's going on, what's changing, identifying any issues that are anticipated to surface, and act on mitigated or remedying problems that arise. It was decided that the monthly SDMC call will be lengthened by 30 minutes, and scheduled so that the first 30 minutes the DMCs can update each other on current activities and then discuss and make a plan to mitigate any issues that may result from these activities, and the second 60 minutes be focused on moving the group along in the yearly committee objectives defined in the HANC yearly work plan. This additional 30 minutes will be crucial

in ensuring each of the DMCs are actively informed on each other's work to avoid either duplicative or conflicting efforts.

In the third quarter the DMC Committee will continue work on above standardization efforts, and also work to expand their focus to address additional objectives listed below (full descriptions can be found in the HANC Strategic Work Plan):

- SDMC Objective #2: Establish a "Data Exchange Standards" book that describes the necessary structure for data interchanges of Assays, Inventories, and Manifests
- SDMC Objective #3: Complete Laboratory Data Systems Harmonization (Build upon Laboratory Harmonization Efforts between FSTRF and SCHARP; Multi-LIMS Manifest Harmonization)
- SDMC Objective #4: Harmonization of MedRA Coding

Evaluation Coordination Objectives and Activities

A Cross-Network Evaluation Committee was established in December 2004 to identify and address opportunities for harmonizing network and site evaluation activities. Evaluation Committee members began by sharing their evaluation handbooks, which include performance measures and standards. DAIDS has subsequently contracted with Concept Systems Incorporated (CSI) to develop an Evaluation System for DAIDS and its funded research programs. HANC has worked with DAIDS and CSI to collect and synthesize Network input for the DAIDS Network Evaluation Project, and involve the Networks and the cross-Network committees and working groups in the project.

The Evaluation Objective #1 in the current HANC work plan is to work with CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes. In the second quarter the following activities have taken place:

- HANC staff worked with Networks, DAIDS and CSI to identify the membership and scope of work for an Evaluation Management Task Force (EMTF) that will be responsible for providing detailed, technical input about indicators, tools, resources and potential measures to be considered for use in the development of the evaluation system plan. Cross-network Evaluation Committee members will participate in the EMTF, as well as representatives from DAIDS and a representative from Community Partners. The EMTF will convene in a face-to-face meeting planned for January 2008.