HIV/AIDS Network Coordination Quarterly Report
Q3 2007-2008: December 1, 2007 – February 29, 2008
Submitted March 29, 2008

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 December1, 2007 – February 29, 2008. 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. 360 individuals currently have active HANC Portal user accounts. Twenty 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:

- User testing and further 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 being slightly redesigned with an anticipated release date in April 2008.
- 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.

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 December 2007, HANC staff have not submitted any new CRS requests. Details of

completed and ongoing 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

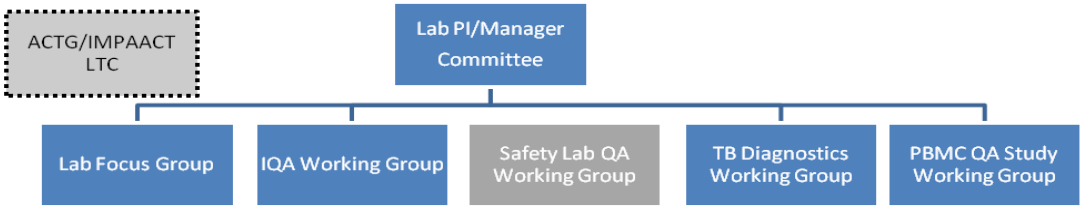
The AIDS Clinical Trials Network Leadership Operations Group (NLOG) and the AIDS Clinical Trials Network Strategic Working Group (SWG) are cross-network bodies established by DAIDS that the HANC office participates in and helps support. The NLOG is charged with implementing and advancing optimal collaborative 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 was held this quarter in February 2008, which included presentation and discussion of HANC and National Institute of Mental Health (NIMH) collaboration on an Adherence-focused meeting. The NIMH has an ongoing interest in adherence issues and would like to to engage the Networks in reviewing the scientific theoretical approaches that have gone into studying and measuring adherence and out of this behavioral science look for common principles to assess adherence (to study drug, to the protocol, of investigator, etc). NIMH, in collaboration with HANC proposes to convene a small, focused meeting for key personnel from the DAIDS HIV/AIDS clinical trials and CHAVI networks to discuss adherence assessment and counseling strategies.

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 did not meet during this quarter, and intends to hold its fourth meeting in May 2008 in Washington D.C.

HANC also facilitated 2 focused monthly conference calls this quarter with the six Network Principle Investigators to address cross-cutting network leadership issues, as well as a face-to-face side meeting at the Conference on Retroviruses and Oportunistic Infections to to discuss HANC leadership transition. Dr. Kublin accepted the position as HVTN Director in February, and is continuing to provide oversight at a reduced effort level to HANC until new leadership can be recruited. A transition and recruitment plan was developed and discussed with the Network Leaders and DAIDS, and recruitment will begin in March 2008.

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. During this quarter the LFG has also developed a comprehensive consensus HIV testing algorithm which the DAIDS Clinical Laboratory Operations Team (DCLOT) has reviewed.

The Immunology Quality Assurance (IQA) working group was put on hold in November pending a 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. Monthly calls were put on hold in November 2007 pending an effort to refocus the group and add operational expertise to the flow cytometry expertise of the past membership. In February 2008, HANC reconvened a smaller group to identify and address issues related more to operational and logistical challenges of conducting assays and proficiency testing at international labs. The group will meet face-to-face in the fourth quarter.

The Safety Lab QA Working Group activity has continued to be 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. In this quarter the response to the Fiocruz, Brazil action plan detailing recommended changes to help them improve their TB processing was received and reviewed. 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 reviewed the reports from these sites visits in February, approved a solicitation announcement for a TB consultant to work with the group; and discussed plans for an additional round of African site visits.

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). The group held one call in December to discuss the data collection form and develop the timeline for study implementation. Further calls this quarter were delayed while

additional statisticians reviewed the study plan and discussions were held with DCLOT and IQA around resource needs for study implementation.

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.
- An online survey was conducted to inform planning for an annual face-to-face meeting of Laboratory PIs, Laboratory Managers, DAIDS Laboratory program staff, and key contractors/partners.
- 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. An Immunology Quality Assurance (IQA) working group teleconferences was held in February for the IQA working group to address issues related more to operational and logistical challenges of conducting assays and proficiency testing at international labs.
    2. The Lab PI/Manager Committee agreed that 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 Viral Load Validation Working Group was convened in October 2007 as a venue for the VQA to work with the networks to agree on what is necessary to include in a validation plan for viral load assays and come to consensus around a common process that will apply to all networks. Two calls were held this quarter to develop and approve an excel template for FDA-approved assays and a Validation Plan SOP. The group also identified international labs with immediate interest in or need for validating a new viral load assay to participate in a pilot of the template and SOP. The Moshi, Tanzania lab will validate the ABBOTT MR2000RT assay with the new SOP and template in their lab. The CAPRISA lab will use the SOP and template to validate the Roche COBAS TAQMAN assay, conducting all of the validation testing in their lab. The Lusaka lab will validate the Roche COBAS TAQMAN assay.
    3. 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.

- 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 the fourth quarter 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 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 Co-Chairs were selected and put into place. The Community Partners leadership structure is now complete and fully functioning. HANC staff worked with the Co-Chairs to develop operational guidelines related to setting conference call agendas and fielding member concerns or questions. Co-Chairs began to lead discussions on group calls.
- A call participant survey was developed to evaluate connectivity and quality of line connections on conference calls.
- *Develop CP member internal communications through improved access to interactive online tools.*
  - An easy mechanism for sharing articles and publications of interest was developed on the CP team site. Weekly summaries of article postings were provided to the group via SharePoint alerts.
  - HANC staff reviewed portal user statistics and provided additional, one on one support to members who continued to report challenges in accessing the portal.
  - The development and use of the Document Review Tool survey and other online surveys for working group were instrumental in supporting group activities during this quarter.
- *Develop relationships within cross-network leadership groups and increase awareness of CP within relevant community groups.*
  - To better represent diverse Network community groups, Community Partners NLOG-SWG representatives explored opportunities for networking with external groups and attending related meetings, conference calls, and conferences. This would in turn enable the reps to better address and represent cross-Network community concerns in NLOG/SWG calls and meetings. A budget line item for rep travel to such external meetings was developed.

- DAIDS staff sought Community Partners on several issues including the Evaluation Measurement Task Force (EMTF) and the Human Subjects Protection Branch (HSPB). Presentations were provided on CP calls and the group engaged in strategic discussions.

- *Identify CP activities that best support the mission and vision of the group.*
  - Discussions about the Y3 budget and work plan began.
  - Planning for a face to face meeting in May 2008 began. The primary agenda topic for the meeting will be development of cross-network community scientific priorities. A subcommittee of the CP Executive Committee was formed to develop the meeting agenda and work with HANC staff on meeting logistics.
  - Sex and Gender data collection- Community Partners members, who were part of an ad hoc working group in response to the Open Letter on Sex and Gender, were invited to serve on a subcommittee comprised of cross-Network Data Management Center group members and DAIDS to explore the question of data collection standardization that is more inclusive of transgender trial participants.

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.* A full draft of the "Recommendations for Community Involvement in NIAID HIV/AIDS Clinical Trials Research" document was completed. The draft included specific recommendations for community advisory board members, research staff, network leadership, and DAIDS through each phase of trial development and conduct. It also included nine community case narratives from the different DAIDS-funded networks.
- *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.
  - A review plan and timeline was implemented. Groups to be included in the review of the document include Community Partners, Network leadership, Network/Global CABS, key stakeholders within the research community and DAIDS staff.
  - Community Partners began its review of the draft document.

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 review of the IMPAACT training modules in terms of cross-Network relevance was completed. Each member was assigned two modules to review, with each module to be reviewed by at least two different members/networks. Upon consideration of the IMPAACT review results, the group began a similar review of the HVTN training materials. The group plans to compare reviews of these different materials to assess any gaps or missing content from a cross-network curriculum perspective.
- *Distribute CAB training materials to relevant network staff and community groups.* As part of the review of network training materials, the group assessed whether those materials should be included in a library of resources for cross-Network use.

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.* A subcommittee of the Executive Committee began exploring how to best approach the development of scientific priorities within Community Partners as part of the face to face meeting planning process.
- *Develop methods and processes for ongoing communication of scientific priorities to network leadership groups and researchers.* Further discussion to take place at the face to face meeting in May.
    - CP began plans for a face to face meeting May 2-4, 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 third 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 and protocol registration training module was completed and is planning for pilot testing with various sites. These materials are being produced under a separate contract under the RAB/RCC office.
- Attribution training evaluation data was gathered and reviewed from the previous DAIDS Regional Training Events held in Lusaka, Zambia and Miami, USA. The feedback from the training sessions was positive with a few suggestions for improvement. Dr. Ling Chin, the new chief of the Safety and Pharmacovigilance team, and Ed Handlesman would like to further customize and revise the attribution training slides making it applicable and accessible to all networks. There is a proposed Attribution training session targeted for the April DAIDS Regional Training Event held in Arlington, VA in which the revised slide set will be presented. One of the main components added into the slide set would be an adverse narrative. DAIDS, with some input from RCC, will create a narrative template that can be modified for different networks. Training would be provided on use of the templates. Once this enhanced attribution training slide set is completed, the working group will continue discussions on how to best disseminate the training so sites can use the training in-network.
- The HANC Training Project Coordinator met with the University of Washington School of Medicine Continuing Medical Education Office to discuss various options available for providing CME credits for

Safety Trainings. Providing CME credits is possible for F2F sessions, the Safety Grand Rounds and in an e-learning environment, however, the trainings provided for accreditation need to be in final form. Once the attribution training slide deck and SGR have been finalized the group will discuss which option (s) would work best to provide CME.

- The CRS task request for the Safety Grand Rounds continues to be under review is has not received final approval.

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 third quarter to support this objective:

- The work of the Admin-fiscal working group continues to be placed on hold until the OIEA posts their final training modules for the WG to compare their modules against in order to avoid duplicating training development efforts.

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

- Training Committee members agreed to share in-network training activities that may be applicable to pluripotent sites. These training activities will be posted on the HANC portal calendar and on the HANC public website.
- A training resources page will become available on the HANC portal and the HANC public website for all to access and be informed on upcoming trainings and general training information.

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 third quarter to support this objective:

1. Risk Reduction Counseling (RRC) training development:
   - The WG continues to make good progress. A baseline needs assessment was done for 12 pilot sites and the data was collected and analyzed.
   - The WG collected several source documentation forms from all of the networks to create a standardized source documentation form for all networks to use. Training will be incorporated into the training materials in development on use of this form.
   - A RFP was sent out to develop vignettes and a SDL. Vendor choices have been narrowed down and negotiations are underway.
   - The working group continued their bi-weekly calls reviewing and discussing all training materials in development. The Executive working group continues to meet monthly.
   - Dr. Fuchs, chair of the HRCT, presented an overview of the HRCT project to the three CDC reps. The CDC reps offered relevant materials they had available for this group to reference. They also agreed to be peer reviewers when the training packet is complete in mid-March.

- Drs Myers and Fuchs submitted an abstract for the IAS conference in Mexico City that summarizes some key points from the needs assessment survey.

2. 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, 1000* individuals have completed training and become certified in GCP and 800* individuals have completed either the refresher or full basic HSP course. 200* have completed the Biomedical and/or Social and Behavioral Responsible Conduct of Research (RCR). *Note: These figures may reflect staff affiliated with multiple networks who may thus be counted more than once in the reporting numbers.
   - Spanish and Portuguese translation for the GCP curriculum has been completed and is available to all trainees.
   - HANC has set-up a team site for the CITI Developers group which consists of 50 global members to collaborate and work on the CITI site content in a central location. Training to be provided to all members in the near future.

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

- The Training Committee is beginning discussions to identify further high priority training needs and additional components to be put in place in order to support a sustainable 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 has still been 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 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. In February the Network Leaders met and discussed the the proposal in the HANC work plan to convene a cross-network Site Management and Clinical Trials Logistics working group. They felt that a single large committee would not be effective in addressing the diverse issues that fall into this category, and that instead we would be better off convening small ad-hoc working groups to address specific issues and involve the individuals with expertise on that particular issue. HANC is currently compiling a list of high priority issues to include in the year 3 work plan based on discussion with the Network Leaders.

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 first quarter, HANC and the DMCs 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. In the third quarter the IT Best Practices document was shared with several clinical research sites to get their feedback before implementation begins.
- Following the finalization of the IT Best Practice Standards document, the DMCs continued discussions to identify the appropriate representatives from the network DMCs, 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.

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 this quarter representatives from SCHARP, FSTRF and CHAVI have reviewed the modules and made recommendations for additions/changes to the module before it is distributed. The HANC office and

the DMCs will be working in the fourth 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. During this quarter an initial conference call was held, with additional follow-up planned for the fourth quarter.

Sex/Gender Data Collection Discussions

- In the second 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 third quarter HANC prepared to convene a Sex and Gender Data Collection working group, with an initial conference call for the group scheduled for early March.

Improved Communication and Coordination between DMCs

- In addition to the monthly calls to move the DMC Harmonization working 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. The monthly DMC 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.

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 third quarter the following activities have taken place:

- Cross-network Evaluation Committee members were identified to participate in the EMTF, as well as representatives from DAIDS and a representative from Community Partners.
- The EMTF, consisting of 27 members, convened a face-to-face meeting January 14-15 2008.
- Four additional working groups were formed from the F2F meeting: the Community/Relevance WG; the Biomedical/Scientific WG; the Operations/Resources WG; and the Communication/Collaboration WG. Each of these working groups consists of network reps and HANC staff and focus on the specified areas of evaluation.
- HANC is represented on the EMTF Planning Group that meets weekly via teleconference