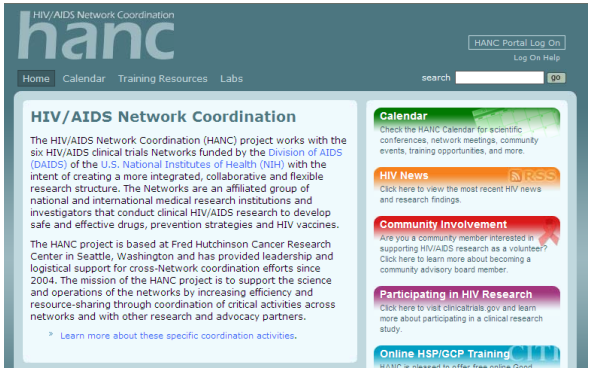
Quarterly Report: Q1 of Year 3, June-August 2008

Infrastructure and Administrative Support

The HANC Public Website

The HANC public website www.hanc.info provides information and resources for collaborators, research sites, and the general public. Functionality and content added to the website this quarter included:

- Information for laboratories, including links to cross-network standard operating procedures (SOPs), the Total Quality Management Program, Virology Quality Assurance Sub-Committee (VQASC) Conference Call Minutes.
- Information for CTU/CRS staff on training events and opportunities.
- Content added to clarify respective roles and simplify contacting OCSO Site Program Officers and Network Leadership Group Program Officers.



The HANC Portal

The HANC Portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. During this quarter we had a net gain of 55 individuals with HANC Portal user accounts, for a total of 451 active HANC Portal user accounts. Four additional team sites were developed for a total of 27 team sites. HANC Portal projects for 2008-2009 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Review user statistics and member survey data collected in Q4 of Year 2 to inform HANC Portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives.	Begin work in Q1 (June-Aug 08) with redesign complete by end of Q2 (Nov 08)	User stats and member survey data was reviewed. A redesign plan was developed and several redesign projects are underway with completion slated for Q2.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held one call this quarter. The AIDS Clinical Trials Network Strategic Working Group (SWG) did not convene a meeting this quarter. Their next meeting will be September 22-23. HANC organized two focused monthly conference calls with the six Network Principal Investigators to address cross-cutting network leadership issues. HANC and DAIDS leadership also holds monthly conference calls to collaboratively identify and address issues and share updates on activities. One of the successes this quarter was the conclusion of the recruitment process for the HANC Director which began in February 2008 when Jim Kublin transitioned to the position of Director of the HIV Vaccine Trials Network. Dr. Kublin has continued to provide oversight for HANC while we

recruited new senior leadership for this project. After a careful search we were delighted that Jeffrey T. Schouten, MD, Attorney at Law, AAHIVS accepted the position of HANC Director. Dr. Schouten will start on September 1st. He has extensive experience both in HIV clinical research and primary care as well as public policy advocacy and is the chair of the board of directors of the American Academy of HIV Medicine. Dr. Schouten has been involved in various capacities with the AIDS Clinical Trials Group, the AIDS Malignancy Coalition and the Neurology AIDS Research Consortium.

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the Network Core Lab Programs.				
Lab PI/Manager Committee	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion and updates from the laboratory working groups.	Ongoing throughout the Year.	The Lab PI/Manager Committee held three monthly calls during Q1. The Lab PI/Mgr Committee also initiated an ad hoc call to address missing CAP panels at the HGNI laboratory.
HANC Support Staff	Create a comprehensive calendar system for HANC Laboratory Working groups	Make HANC-coordinated conference call information and materials available and easily transferrable to working group members from one convenient location. Streamline procedures for Laboratory Project Coordinator.	Q1 complete and implement.	Instituted a new comprehensive HANC Laboratory Working Groups Calendar on the HANC Portal. The new calendar provides all the information needed for each conference call, can be synced with or exported to most calendar programs, and sends email alerts with call information and changes. The calendar can be used for posting other cross-network lab events.
HANC Support Staff	Redesign Laboratory Coordination and Laboratory Resources portions of the HANC public website	Provide clear information to the general public and laboratories about the working groups and their roles and make various resources available to labs.	Q1 (Aug 08) Plan and present project to IT staff; Q2 (Sept 08) complete and launch new web pages.	Completed project description and submitted to IT staff.
Objective #2: Ensure standard quality assurance for all of the protocol-specified assays conducted in DAIDS-sponsored network clinical trials across networks and other partners through the development and implementation of a Total Quality Management (TQM) Program				
HANC Staff Support	Develop overall structure and outline for the TQM document.	Provide a framework for the QA working groups, LFG and the Lab PI/Manager Committee for the review and completion of the TQM document.	Q1 (Aug 08) complete outline.	The outline was completed.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Lab Focus Group, Lab PI/Manager Committee	Review the TQM proposal and revise as necessary before taking the next steps toward full implementation.	Consistent clear guidelines for responsibilities, monitoring, data and communication flow across and within QA areas.	Q1 (Aug 08) review with LFG; Q2 (Sept 08) present to Lab PI/Mgr Committee; Q3 (Dec 08) Finalize	The LFG has been unable to review the modified TQM document due to other more pressing issues. The LFG is scheduled to begin review Sept. 2008.
IQA CD4 Working Group	Review and modify the IQA CD4 Working Group Guidelines to reflect current practices and goals for publication on the HANC public website.	Clarify and outline responsibilities, monitoring, data and communication flow within the IQA CD4 PT program as part of the TQM document.	Q1 (Aug 08) review and send to IQA for completion; Q2 (Nov 08) Review and finalize.	Revised IQA CD4 Working Group Guidelines. Improved communication among IQA, labs, and the Networks: Drafted, reviewed and sent an explanation of how to read and interpret UK NEQAS reports to participating labs. Implemented a system to notify Networks of new postings on the IQA website. Changed the alert notification so networks are notified of two unsatisfactory results in a row or one missing round of testing. Populated new IQA Website with reports and lab contact information. Posted IQA information on the ACTG website on the public area of the IQA website.
IQA CD4 Working Group	Maintain a structure, processes and a forum for consistent communication about IQA CD4 labs.	Consistent quality control of IQA CD4 testing at Network-affiliated laboratories.	Ongoing throughout the year.	Discussed/resolved testing issues at ten labs
IQA PBMC Cryo QA Working Group	Develop IQA intervention, corrective action, remediation and training approach; formulate communication scheme and document as part of the TQM document.	Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories.	Completion target Q3 (Dec 08)	Sent memo to labs providing information about the program, the requirements and how to enroll. Instituted standard nomenclature for participating labs including state and LDMS #. Completed IQA Internal studies into intra-IQA variability and shared the results with the group. The group is discussing the practical ramifications of the data and follow-up studies. Reviewed example memo that the IQA sends to labs that summarizes lab-IQA communications and makes recommendations to the labs. Developed a list of unaddressed needs, including formulation of communication guidelines.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.				
Ad hoc Brazil Panel Shipping Group	Develop and implement a centralized safety panel shipping scheme for Brazil.	Timely and reliable delivery of safety panels to labs in Brazil	Q1 (Aug 08) Obtain cost estimates for shipping schemes; Q2 (Nov 08) Select and Implement new shipping scheme; Q4 Assess effectiveness.	Gathered information and submitted it to World Courier for estimates.
Lab Focus group	Complete HIV Diagnosis Algorithm.	Consistent diagnosis of HIV for network protocols.	Q1 (Aug 08).	Completed and posted the HIV Diagnosis Algorithm on the LFG team site for network lab use.
PBMC SOP Implementa-tion Working Group	Develop and implement a cross-network/CHAVI PBMC Processing SOP.	Consistent PBMC processing at network and CHAVI labs.	Q1 (Aug 08) Develop and begin review of SOP; Q2 complete review (Sept 08); Q2 (Oct 08) distribute to reviewing labs; Q2 (Nov 08) Review lab feedback; Q3 (Dec 08-Feb 09) Finalize and implement SOP.	Held three calls to discuss the complete reformatting of the SOP, review most of the changes, recommend further changes and clarifications, and preliminarily discuss implementation strategies.
Viral Load Validation WG	Implement a cross-network Viral Load Validation template and SOP.	Consistent viral load validation at Network-affiliated laboratories.	Completion target end Q4 (June 09).	Collected data from most test sites and provided monthly updates for the Lab PI/Manager call. Data is uploaded into an SAS database as it is received.
Objective #4: Continue collaborating amongst the Networks, HANC, DAIDS and SMILE to improve TB diagnostics, TB proficiency testing and participation of labs with TB diagnostic capacity in Network protocols where TB is a component.				
TB Diagnostics Working Group	Pursue collaboration with PATH.	Test new TB diagnosis technologies at network sites.	Q1 (Aug 08) Meet with PATH; Q2 (Sept 08) Discuss collaboration on TB CDRC; Q3-Q4 Test technologies at network sites.	Met with PATH to discuss opportunities for collaboration and planned another meeting to further discuss collaboration, including a proposal to develop a “Tuberculosis Clinical Diagnostics Research Consortium” through NIAID.
TB Diagnostics Working Group	Plan site visits to TB diagnostics labs.	Evaluate TB diagnostics labs for capacity to participate in network protocols and serve as regional training centers.	Ongoing throughout year.	Began planning site visits to labs in Botswana and India for the end of September/beginning of October.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
TB Diagnostics Working Group	Develop draft language for network protocols that use TB diagnostics.	Provide standard language for networks to use in protocols that use TB diagnostics.	Q1 (Aug 08) Draft language; Q2 (Oct 08) Review draft; Q2 (Nov 08) Finalize language.	The project was put on hold in favor of discussions with PATH.
Objective #5: Complete the PBMC QA study for optimization of a PBMC Cryopreservation Protocol, develop a PBMC Cryopreservation SOP based on the data generated, and work with a cross-Network working group to implement this SOP.				
Cryo Optimization Study Working Group	Complete study for optimization of PBMC Cryopreservation Protocol, develop a new standard SOP based on data generated, and implement the SOP.	Consistent optimized procedures for the cryopreservation of PBMCs at Network-affiliated laboratories.	Completion target end Q4 (June 09)	Approved a new study design; phase one of the study will begin Sept. 2008 with all data collected by Dec. 2008.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop a community science research agenda.				
Community Partners	Draft a clear written outline of the project scope, intent, timeline and criteria to determine project success. Identify CP members willing to work on this project. Develop the research agenda.		Q4, target completion, perhaps beyond	Discussions are ongoing regarding the development of a science research agenda.
Objective #2: Finalize and disseminate the "Recommendations for Community Involvement in NIAID HIV/AIDS Clinical Trials Research."				
Community Recommendations Working Group	Finalize document and create an executive summary. Create a distribution plan. Distribute recommendations document to network leadership and community groups.	Improved community input into the planning and implementation of research activities.	Q1, target completion Q2 (Nov 08)	Document was edited and was just reviewed by a technical editor and the working group needs to meet to accept edits and finalize document for completion.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Utilize the Community Training Working Group to share existing CAB training materials, identify and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules.				
Community Training Working Group	Post materials from the training library on the HANC public website. Partner with groups to incorporate a human rights perspective into capacity building and research participation. Create simple training materials from existing content on what Community Partners is and the science and structure of the networks. Draft proposal for contract technical writer to compile materials for "Understanding the clinical research process" into a single standardized module relevant across networks.	Common CAB member understanding of basic concepts in HIV disease, clinical trials methodology, and CAB role. Improved training quality and consistency.	Materials sharing ongoing; Development of standardized module beginning in Q1	The working group drafted a technical writer proposal and the Executive Committee approved the funding for the technical writer proposal.
Objective #4: Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact.				
Community Partners	Develop a continuous quality improvement process for CP. Identify objective metrics and mechanisms for evaluating the impact of CP activities.	Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.		Discussions are ongoing to form a group to address this objective.
Objective #5: Review site-level CAB funding and support in the current grant period to identify areas where funding and support mechanisms are working well and areas where there are problems or opportunities for improvement.				
Community Partners	Research current site/CAB funding structure to understand the system. Partner with the network leadership to assess how the site funding mechanism has impacted community involvement at the network, CTU and CRS level. Identify expectations for CAB support and funding that tie into cross-network community evaluation and make actionable recommendations to network leaders and DAIDS.	Adequate site-level CAB support.		Discussions are ongoing to form a group to address this objective.

Training Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Identify and provide access to cross-network standardized training for high priority topic areas.				
Training Committee	Identify and discuss training needs and ways to provide access to trainings. Use HANC portal team site for information sharing, training announcements, training requests, and document development.	To address training needs	Ongoing throughout the Year	Training Committee has begun to review data provided by PPD from the Clinic Assessment Tool, including site suggestions of additional training needs. Next steps are to look at this data on a network, committee and DAIDS level as well as by geographical area.
Objective #2: Continue the development of core training materials addressing risk reduction counseling in biomedical prevention and treatment trials.				
Risk Reduction Counseling Training Working Group	Meet on regular calls to develop and review the training curriculum and ensure the project stays on track and within budget.	Improve the quality of risk reduction counseling in biomedical prevention and treatment trials.	(Aug 07-Apr 09)	Produced a pre-pilot eLearning module in English and Spanish (built in Moodle LMS) on Stages of Behavior Change previewed by OPCRO Leadership in June 2008. Programmed the AETC skills evaluation strategy which includes four vignettes, two in English and two in Spanish. Launched pre-pilot assessment of 50+ trial staff from the US, South Africa, Uganda, Kenya, Tanzania, Rwanda, India, Thailand, Puerto Rico and the Dominican Republic. Submitted a supplemental CRS request for this task to obtain additional funding. Began planning the Training of Mentor session to be held in conjunction with the November HVTN meeting.
Objective #3: Develop a modular administrative and fiscal training program.				
Admin-Fiscal Training working group	Reconvene the working group to review grants management on-line trainings recently made available by the OIEA and identify gaps where additional training is needed.	Avoid duplication of effort and provide a comprehensive grants management training curricula to all CTU/CRS.	TBD	On hold

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #4: Engage the networks and DAIDS in implementing a cross-network training program addressing issues of sustainability.				
Training Committee	Identify ways to address implementing a sustainable training program. Collect and review data from training needs assessments conducted by DAIDS and the networks to identify key training/capacity building needs. Continue review of evaluation data from DAIDS Regional Training Events.	Provide financially and operationally sustainable training support to sites.	Ongoing	Summaries being provided for review on the Clinic Assessment Tool (see progress in Objective 1). DAIDS providing reports on the most recent DAIDS Regional Training Events to review.
Objective #5: Collaborate with the cross-network Lab PI/Manager Committee to provide access to on-line GCLP training once it is developed				
See Laboratory Objective #3.				
Objective #6: Collaborate with the cross-network DMC Harmonization working group and Community Partners to develop and provide training to site staff to better prepare them to be sensitive on transgender social and biomedical issues and interact more appropriately with transgender trial participants				
See DMC Objective #5.				

Site Management & Logistics Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: In collaboration with relevant network staff, OPCRO and OCSO, develop a communication plan and process flow for how site management issues will be identified, addressed, and resolution communicated to all relevant stakeholders.				
Network staff, OPCRO and OCSO	Develop a communication plan and process flow for how site management issues will be identified, addressed, and resolution communicated to relevant stakeholders.	Increase the efficiency and speed of resolving site management issues.	Begin work in Q2 (Sept 08)	No work planned for Q1.
Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS offices to identify and address priority site management issues.				
Network Leaders, OCSO, OPCRO	Identify an evolving list of site management issues and opportunities. Work closely with network staff, OPCRO, OCSO and other DAIDS offices to address priority site management issues.	Improve communication and site operations.	Begin work in Q2 (Sept 08)	Conversations continued between OSCO and Network Leaders regarding site funding issues. List development will begin in Q2.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Partner with the National Institute of Mental Health (NIMH) to bring together the DAIDS-funded HIV/AIDS clinical trials networks and a few other partners to address critical cross-cutting issues in prevention adherence.				
HANC and NIMH staff	Coordinate a cross-network Steering Committee to assist NIMH in planning the agenda for the meeting. Hold a one and one-half day face-to-face meeting in Bethesda, Maryland in July 2008 with cross-network representatives.	Explore lessons learned from treatment adherence and apply them to increase adherence in HIV prevention in biomedical and other trials.	Q1 - meeting to be held July 08. Follow-up activities may be ongoing.	Steering Committee held one call in Q1 to finalize the agenda. A successful meeting was held July 15-16 with 41 participants. A full meeting report will be made available in early September.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Implement Information Technology Best Practice Standards developed in Year 2 at DAIDS Clinical Trials study sites and affiliated laboratories and monitor infrastructure changes.				
DMC Harmonization Working Group	Implement Information Technology Best Practice Standards developed in Year 2 at DAIDS Clinical Trials study sites and affiliated laboratories. Monitor infrastructure changes.	Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems.	Begin work in Q1 (June 08); complete in Q2 (Nov 08)	Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. It Best Practices shared with OCSO, OPCRO and DAIDS Leadership for feedback prior to distribution in Q2.
Objective #2: Establish an "Input/output transmission Standards" book to describe necessary structure for data interchanges of assays, inventories, and manifests.				
DMC Harmonization Working Group	Establish standards for clinical data formats associated with case report forms (CRFs). Establish standards for laboratory assay data formats associated with immunological and genomic sequences assays. Initiate discussions among the Networks surrounding Electronic Data Captures at sites and Data Management Centers.		Continuing from work in Year 2; Q2 begin more focused effort.	DMCs held a review and discussion on 7/14 of remote data entry systems. Discussions regarding Electronic Data Capture are ongoing.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization.				
DMC Harmonization Working Group	Maintain code mappings across LIMS systems and modify specimen inventory data elements as requested by SCHARP to track and QA data. Work with individual collaborating partners to ensure that previously identified common data elements are included and supported in electronic manifest files readable across multiple systems and reported back to SCHARP in an inventory data feed.	Electronic manifest files readable across multiple systems and reported back to SCHARP as part of an inventory data feed.	Ongoing	No information to report from Q1.
Objective #4: Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization.				
MedDRA working group	Organize lead coders with formal MedDRA training into a MedDRA working group chaired by the DAIDS MedDRA consultant. Conduct monthly conference calls and meet annually. Periodically exchange and review new MedDRA codes in light of DAIDS enterprise coding policies. Review nominations for the DAIDS-ES synonym list. Collect and review change requests for submission to the MSSO. Issue consensus statements as appropriate.	Consistent MedDRA coding of adverse events across studies and a higher MedDRA coding standard.	Ongoing	MedDRA working group met monthly to review and address MedDRA issues.
Objective #5: Identify issues and determine how data collection for transgender participants in DAIDS-funded HIV/AIDS clinical trials should be best conducted.				
DMC Harmonization Working Group	Work with the HVTN Transgender working group to identify issues around transgender participation in clinical trials and further develop improved data collection questions.	Improve data collections tools to better capture data on transgender participants while respecting their unique concerns.	Ongoing	On hold over the summer.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #6: Identify site DMC training and support needs and in collaboration with the cross-network lab and training groups develop recommended funding and implementation suggestions to address them.				
DMC Harmonization Working Group, Training Committee	Collaborate with the cross-network Training Committee to identify and address data management training needs.	Inform training plans and ensure that sites receive the data management training necessary to participate in clinical trials.	Begin work in Q2 (Sept 08)	The DMC Harmonization working group identified specific training they would like to see provided in a standardized manner. HANC initiated discussions with DAIDS staff and OTIS around IT/DMC training.
Objective #7: Explore the role of the Office of Technology Information Systems (OTIS) which manages technologies supporting NIAID biomedical research programs to establish an understanding of how they interact with the networks and sites and formalize communication or coordination with them.				
DMC Harmonization Working Group	HANC will establish a relationship with OTIS staff and invite them to present an overview of their activities. The DMC Harmonization working group will work with OTIS to identify opportunities for collaboration and ongoing information sharing.	Formalize communication or coordination between the DMCs and OTIS.	Begin work in Q2 (Sept 08)	HANC initiated communication with OTIS leadership in August 2008 and invited them to begin discussions with the DMCs in September.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Work with CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes.				
Evaluation Measurement Task Force	Convene a F2F meeting in June to review each working groups work accomplished to date and identifying the next phase of work. Hold monthly calls with each working group and CSI to progress the work of developing an evaluation system.	Develop evaluation metrics and processes to evaluate DAIDS and Network success and identify opportunities for improvement.	Ongoing throughout the Year	The EMTF convened in June and developed a broad set of evaluation questions based upon the most important success factors identified by key stakeholders (including network leaders and staff). Potential methods and data sources were also identified and agreed upon. The EMTF is preparing to present the work to date to the Network Leaders Operations Group in September.