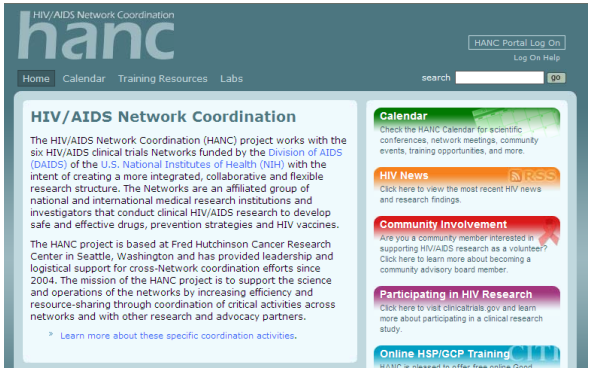
Quarterly Report: Q2 of Year 3, September-November 2008

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:

- Virology Quality Assurance (VQA) Resources
- ACTG/IMPAACT Laboratory Manual
- Information for CTU/CRS staff on training events and opportunities.
- Contact forms for 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 38 individuals with HANC Portal user accounts, for a total of 489 active HANC Portal user accounts. Six additional team sites were developed for a total of 33 team sites. HANC Portal projects for 2008-2009 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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)	Redesign projects completed in Q2 include the addition of member profiles, a program highlights web part, additional portal training content, a HANC contact system providing HANC member contact and working group membership information, and access through the HANC portal to the DAIDS-ES Master Contact System.
HANC staff	Feasibility of linking to the DAIDS-ES document library of all approved network protocols on the HANC portal	Ready access to all network approved protocols for HANC portal users.	Feasibility determination in Q3	Proposed to DAIDS and the network leaders in November 2008.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held two calls this quarter. The Evaluation Measurement Task Force presented on the September 17, 2009 call and the NIMH presented the report from the Prevention Adherence in the DAIDS HIV Clinical Trials Networks meeting on the November 19, 2009 call. The AIDS Clinical Trials Network Strategic Working Group (SWG) convened a meeting September 22-23, 2008. The ACTG presented its scientific agenda and protocol A5257. Jeffrey Schouten presented a session titled "Questions in HIV Clinical Research" which focused on the following topics:

- Multi-faceted prevention intervention trials. (i.e. microbicide, vaccine, PrEP and/or behavioral interventions.)
- The incorporation of randomized prevention interventions into therapeutic trials.
- People with acute/early HIV infection identified in an ongoing vaccine, microbicide, and prevention trials, or the partners of subjects in therapeutic trials.
- Studies on the timing of initiation of antiretroviral therapy (Informational).
- Studies of the natural history, prevention and treatment of cervical and anal HPV infection.
- Cross-network DNA banks.
- Prevention trials for AIDS or non-AIDS-associated malignancies.

HANC organized 3 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.

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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.	Held two monthly calls during Q2 to discuss what kinds of reports should be necessary through the HANC Lab Database, resources that should be available on the Laboratory Resources section of the HANC public website, whether or not hold a face-to-face meeting, the components of the new CPQA program, a review the TQM Overview, and whether or not to form a new cross-Network group for viral load cut-off values. A Webex demonstration of the new HANC Lab Database was also given.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
HANC Support Staff	Plan and conduct HANC Laboratory Face-to-Face Meeting	Provide a forum for discussion of laboratory-specific topics that cannot be held in the usual conference call format.	Q3 (Dec 08) Hold meeting.	The Lab PI/Manager Committee determined that a face-to-face meeting was not necessary. Instead they suggested that the HANC Director and HANC Laboratory Project Coordinator attend network conferences as possible and appropriate.
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 IST staff; Q2 (Sept 08) complete and launch new web pages.	Updated the Laboratory Resources portion of the HANC public website with VQA Resources and the ACTG/IMPAACT Lab Manual. VQA Reagent Order Form completion is pending further information from the VQA, Laboratory Coordination page is pending further IST work.
CPQA Advisory Board, Steering Committee, Cross-Network Lab Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion of Clinical Pharmacology Quality Assurance -related issues	Ongoing	Held introductory calls for each CPQA group.
HANC Support Staff, Lab Focus Group and IST Staff	Develop and maintain a HANC Laboratory Database for network-affiliated international labs	Provide a common resource for the storage and maintenance of laboratory information; develop consensus laboratory names to ease communications among network laboratory staff and contractor staff	Q1 (Aug 08) Collect and verify laboratory information and plan database construction; Q2 complete and implement database	Completed and launched version 1 of HANC Laboratory Database on HANC Portal; conducted Webex tours with two working groups (Lab PI/Mgr and IQA CD4); started planning for version 2.
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				
Lab Focus Group, Lab PI/Manager Committee	Review the TQM proposal and revise 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	Completed review of the TQM Overview. Lab/PI Manager Committee approved it and it is now posted on the HANC public website. The LFG will review the Safety EQA Guidelines Dec 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.	Reviewed and revised the guidelines. A final review will be completed December 2008.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 14 labs.
IQA Cryopreservation Proficiency Testing Advisory Group (ICAG)	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)	Drafted and reviewed memos to labs that outline the processes for submitting samples for regular rounds of testing and for pre-qualification of labs. Final drafts are pending. Determined that ICAG guidelines should be based on IQA CD4 Working Group guidelines. Draft of ICAG guidelines is pending completion of IQA CD4 guidelines.
Quality Assurance Sub-Committee (QASC)	Post QASC guidelines on the HANC public website as part of the TQM document.	Clarify & outline responsibilities, monitoring, data and communication flow within the Virology Quality Assurance (VQA) PT program as part of the TQM document.	Q2 (Dec 08) Draft and review; Q3 (March 09) Complete and post	Completed first draft, which was reviewed by QASC and VQA.
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.	Designed and tested a trial shipping scheme that utilized World Courier and substituted Accutest panels for CAP panels where appropriate. The test round was highly successful including highly reliable package delivery and the group decided to implement the new scheme for 2009, at an estimated cost savings of $58,000 per year.
PBMC SOP Implementation Working Group	Develop and implement a cross-network/CHAVI PBMC Processing SOP.	Consistent PBMC processing at network and CHAVI labs.	Q1 (Aug 08) Develop SOP & begin review; Q2 complete review (Sept 08); Q2 (Oct 08) distribute to reviewing labs; Q2 (Nov 08) Review lab feedback; Q3 (Dec 08-Feb 09) Finalize & implement SOP.	Held five hours of calls to review group and lab feedback to the SOP. A completed review and drafting of network-specific quick guides is pending.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Laboratory Focus Group	Identify which analytes used by the Networks require reference ranges and determine which of these reference ranges require local or regional definition; work with sites to ensure that where necessary local reference range studies are designed, funded and conducted.	Consistent analytic reference ranges and a common resource for all networks	Q2 (Oct 08) Determine feasibility of project	Held a joint LFG/SCHARP/FSTRF call to clarify how analyte reference ranges are currently collected and stored at the two DMCs, and to determine whether or a shared system would be feasible. Determined that cross-network harmonization of analyte reference ranges is not feasible and abandoned project.
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).	Reviewed 2 example validation reports and provided feedback to the VQA. Decided to send future blinded reports to the QASC for review, and unblinded reports to network managers.
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) Met with PATH; Q2 (Sept 08) Discussed collaboration on TB CDRC; Q3-Q4 Test technologies at network sites.	ACTG and IMPAACT submitted an application for the TB CDRC with PATH.
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.	Reviewed site visits reports from four labs in India, planned site visits to three labs in Peru for January, 2009. Began discussions of possible site visits in Thailand.
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.	Postponed discussion of language for network protocols in favor of more urgent issues.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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)	Study in progress.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Develop a community science research agenda.				
Community Partners Scientific Priorities Working Group	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.	Develop a community science research agenda that incorporates various network and community scientific priorities. Support SWG reps in review of protocols.	Q4, target completion, perhaps beyond	Held introductory call and discussed the purpose, role and future of the group.
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) Target completion (Jan 09)	Document was edited by a technical editor and then reviewed again by HANC and DAIDS leadership and working group. Document was sent back to technical editor for final edits and FINAL Executive Summary and full document will be distributed electronically.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 Community Partners 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 Target completion to hire technical writer (Dec 08)	Solicited technical writer applicants to compile materials. Reviewing information provided by candidates and in process of selecting a final candidate for the technical writer position.
Objective #4: Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact.				
Community Partners Evaluation Working Group	Develop a continuous quality improvement process for CP. Identify objective metrics and mechanisms for evaluating the impact of CP activities. Become the core group of the Evaluation Measurement Task Force (EMTF) in collaboration with HANC and CSI.	Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.	Ongoing throughout year.	Held introductory call and discussed the purpose, role and future of the group.
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 Site-Level Funding Working Group	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. Develop a training tool for CABs that would cover goals, priorities, budget and step-by-step process on how to start a CAB.	Adequate site-level CAB support.	Ongoing through the year.	Held introductory call and discussed the purpose, role and future of the group.

Training Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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	The Committee I sinterested in creating a new cross-network training needs assessment after first looking at networks' previous and current training needs assessments, which have been posted on the Committee team site. The Committee is currently reviewing these materials prior to discussion in January '09. Representatives are identifying data relevant to cross-network training areas of need vs. those specific by network or project. Networks are also being asked which tools were used to gather data for their needs assessments. A round robin discussion forum was set-up at the beginning of each Training Committee call to provide an opportunity to share training activities and issues and ask questions of other networks.
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-Dec 09)	The curriculum development team and the e-learning vendor, SMI, held 4 focus group calls (3 international, 1 domestic) with those who participated in the pre-pilot. The international sites which we could not set-up a call with provided feedback via email. The feedback received will be provided in an executive summary and implemented into a new proposal from the AETC and the e-learning vendor prior to rolling out our pilot program to the 12 pilot sites of this project. Extensive planning by the Training of Mentor (TOM) planning group occurred in Sept.-Nov. for the TOM session that took place Nov. 16-17 in conjunction with the HVTN meeting in Seattle. 44 site staff, both international and domestic attended the training. Out of the 12 pilot sites for the HRCT project, six were randomized to have a mentor attend the TOM. The next phase of the HRCT study will continue as planned which is comparing Self Directed Learning (SDL) vs. SDL+ having a mentor. Full funding for the supplemental request is still pending.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 comprehensive grants management training curricula to all CTU/CRS.	TBD	On hold
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	See progress in Objective 1. DAIDS continues to provide progress updates and reports on DAIDS Regional Training Events (DRTE) as well as gather feedback on scheduling upcoming DRTE's from the networks. DAIDS is also implementing on-line training webinars to make required trainings more accessible (i.e. QM and EAE training). The DAIDS Learning Management System will be rolled out to the networks for use. This system is a repository for training serving as a central location for staff across enterprises to register, access and record training in their learning history. This tool could help networks better track who has been trained on which topics within and across networks.
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 Q2
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)	HANC met with Richard Hafner after SWG and has had calls with Manizhe Payton to facilitate communication with network leadership about site performance issues and site PI changes. Draft SOPs on records retention were shared with network leaders and operations centers.
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) and ongoing	HANC will conduct every other month calls with OPCRO and OCSO and monthly calls with OCSO to address site management issues.
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.	Meeting report finalized and presented to the NLOG on their call on November 19, 2008. Plan to draft a mission statement and recruit for a cross-network/IC working group to pursue report's recommendations in Q3.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 were shared with NIAID Office of Technology and Information Systems (OTIS) in Q2 for feedback. Suggested changes will be incorporated in early Q3; the IT Best Practices will inform IT training in development by DAIDS staff in Q3.
Objective #2: Establish "Input/output transmission Standards" 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.	Remote data entry systems were addressed in Q1. Discussions regarding Electronic Data Capture are ongoing.
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	DMCs have completed step 1 sign-off on the final proposal for the cross-LIMS manifest project. This involved approvals from HVTN, Labware, FSTRF and SCHARP. The next step is to get DAIDS and Seracare to sign off on the proposal as well and then they will begin programming efforts. John Hural from the HVTN is leading the effort to get support from DAIDS and to gather the final signatures.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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. AIDS Event Definitions project is now a working group with its own team site. The intent is to develop AIDS-event queries in order to better review safety data to determine HIV-related events in relation to safety profiles. Ideally SMQs will be tools applicable to both data sets if the DMCs want to combine data with that of another network. The working group held 3 combined meetings / calls this quarter. Kathy Huntley has mapped CDC and WHO guidelines and drafted example SMQs for the DMCs and statisticians to consider in Q3.
Objective #4: 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	Working group was not convened this quarter. Activities in Q3 will resume pending information from HVTN Transgender working group in follow-up to a transgender training conducted in October.
Objective #5: 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)	Held data management training focused call in Oct. '08 with DAIDS training staff and OTIS representatives. DAIDS and OTIS staff will develop training curriculum in collaboration with the DMCs in Q3/Q4. Data Collection module under revision by OTIS; decision about dissemination anticipated in early Q3.
Objective #6: 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	Establish a relationship with OTIS staff and invite them to present an overview of their activities. 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)	OTIS presented an overview on an Oct. '08 call which included discussion of collaboration activities and plans for addressing training needs together. Chris Whalen from OTIS is joining regular DMC Harmonization calls.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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	Representatives from each EMTF working group presented work-to-date to the NLOG in September '08. HANC/CSI/DAIDS have weekly calls. The Scientific Agenda and Objectives WG held a call this quarter and are currently collecting information to inform a detailed analysis plan to address questions generated by the EMTF: How do DAIDS and the DAIDS-funded networks set and revise their scientific agendas? How do networks track the dissemination of results? How are the results from studies disseminated? When and to whom? The Communication, Collaboration and Harmonization WG comprised of HANC staff are drafting a survey and stakeholder interview questions to address the question generated by the EMTF: How well is HANC supporting and facilitating cross-network coordination? Community Partner's evaluation subcommittee convened and will assist on the community and participants working group of the EMTF. The EMTF work plan was presented to the HVTN Evaluation Committee at HVTN meeting on November 20, 2009.