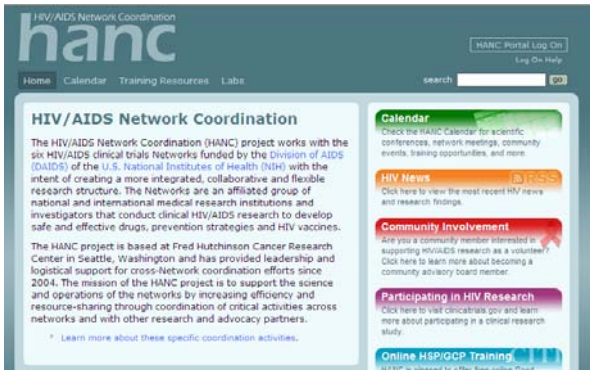
Quarterly Report: Q3 of Year 3, December 2008-February 2009

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:

- Detailed information about cross-network coordination of laboratory processing
- OSCO SOPs
- Google analytics for site usage data.

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 70 individuals with HANC Portal user accounts, for a total of 559 active HANC Portal user accounts. Five additional team sites were developed this quarter, including the new Behavioral Sciences Working Group, for a total of 38 team sites. HANC Portal projects for 2008-2009 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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)	Google analytics have been installed on the HANC public web site and monthly usage reports from the HANC portal and team sites are being generated.
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	HANC is working with Digital infusion to determine workability of a web feed to access the protocol reports and pass HANC portal users through to the DAIDS-ES portal to access approved versions of network protocol documents.
HANC staff	HANC portal user survey	Determine user satisfaction and awareness of HANC projects and working group activities.	Survey designed in Q3 and to be distributed in Q4	Survey design completed in Q3.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held 1 call this quarter during which major network protocols in development were reviewed and the HVTN's Legacy Project presented a review of their program. The AIDS Clinical Trials Network Strategic Working Group (SWG) convened a meeting in Montreal during CROI where the ACTG presented its scientific agenda and priorities for the future and the HPTN presented a protocol design for a "test and treat" approach for prevention of HIV transmission. HANC organized 2 focused monthly conference calls with the six Network Principal Investigators to address cross-cutting network leadership issues. HANC and DAIDS leadership also held monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC held monthly calls with OCSO leadership and one call with OCSO and OPCRO.

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 one call during Q3 to discuss recommendations for viral load testing, DCLOT recommendations for quality control of waived tests, quality and consistency of PPD audits, use of expired reagents, and GCLP standards.
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. Q4 (May 09) Launch VQA Lab Reagent Order Form	VQA Reagent Order Form completion is pending further information from the VQA.
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; Q3 submit requests for database upgrades; Q4 complete database upgrades	Requests for upgrading the database to include sortable and exportable results submitted.

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	Review and modify the Safety Lab Quality Assurance 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 Safety EQA program as part of the TQM document.	Q3 (Feb 09) review; Q4 Send to DAIDS and SMILE for approval	Initiated review February 09.
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 and Q3 Review; Q4 Finalize.	Guidelines are awaiting final review from one network before posting.
IQA CD4 Working Group	Maintain a structure, processes and a forum for consistent communication about and performance review ofIQA CD4 labs.	Consistent quality control of IQA CD4 testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 2 calls during which testing issues at 7 labs were discussed and resolved.
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 Q4 (May 09)	Discussed quality control at repositories and implications for IQA PBMC Cryo PT Program.
ICAG	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA PBMC labs.	Consistent quality control of IQA PBMC cryopreservation testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 3 calls during which the group discussed: • How to address discrepancies in data submitted by labs. • The HVTN Cryopreservation PT Program and how to accommodate shared sites.

ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository	Reliable results in functional and phenotypic assays.	Q3 Initiate plan development; Q4 Finalize plan, initiate testing of current samples, pilot testing of incoming samples	Developed a plan for the quality control of existing samples at BRI and for ongoing and future studies.
ICAG	Develop ICAG 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 PBMC Cryo PT program as part of the TQM document.	Q3 Draft guidelines; Q4 Finalize and post	Guidelines were drafted and then put on hold in favor of more urgent issues.
CPQA working groups (Advisory Board, Steering Committee and Lab Group)	Maintain a structure, processes and a forum for consistent communication about the CPQA PT program and labs.	Consistent quality control of pharmacology testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 7 calls during which the CPQA working groups: • Reviewed the AVR SOP Review Process. • Discussed possible alternative accuracy assessments when external PT isn't available. • Discussed tenofovir-diphosphate reference standard issues for assay development and validation and for intracellular tenofovir-DP measurement in patient samples. • Communicated program details to relevant parties.
Quality Assurance Sub-Committee (QASC)	Maintain a structure, processes and a forum for consistent communication about and performance review of VQA labs.	Consistent quality control of virology testing at network-affiliated laboratories.	Ongoing throughout the year.	Held 3 monthly calls during which proficiency testing reports and cumulative performance summaries were reviewed.
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.	Q4 (March 09) Complete and post guidelines.	Initiated third revision and review of guidelines.

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.				
ACTG IMPAACT/LTC and HANC Support Staff	Redesign ACTG/IMPAACT LTC team site and document library to accommodate minor versioning of documents and additional document properties, improve instructions for use, and provide a Sandbox for trying document library functions.	Facilitate development, review and revision of the ACTG/IMPAACT Laboratory manual.	Q3 Complete redesign.	Completed document library and team site redesign. Held two webinars to demonstrate the team site and document library functions to LTC members. Compared published versions to draft version in the document library and generated a list of documents for the LTC to review.
LFG	Recommend and implement new real-time viral load assay for use in network protocols with viral load primary endpoints	Reliable and consistent data collection.	Q3 Review VQA validation data, choose a viral load platform and communicate recommendations to sites, networks, and DAIDS; Q4 Complete memorandum of understanding	Reviewed VQA validation data. Chose a viral load platform. Communicated recommendations to sites, networks, and DAIDS.
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) Review and finalize SOP and quick guide and distribute for network review; Q4 (Mar-May 09) Finalize and implement SOP	Held three hours of calls to review group and feedback of SOP and quick guides, and discuss issues surrounding implementation. A review by network personnel is pending.

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 Notification from CDC.	Awaiting notification on CDRC application.
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 three labs in Peru for January, 2009. Continued 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.	Q1-2 Draft language; Q3 (Feb 08) Review draft; Q4 Incorporate alternative EQA methods and specimen collection and transport into the guidelines.	Reviewed first draft and made recommendations for second draft.
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 Q3
Objective #1: Develop a community science research agenda.				
Community Partners Scientific Priorities	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.	Identify network and community scientific agendas/priorities and identify gaps, overlaps and provide input from the community perspective in shaping agenda items.	Q4, target completion, perhaps beyond	Held two conference calls and the working group has been working on developing a matrix with all the network priorities. Each network representative on the working group is obtaining community input on the scientific priorities and that information will be placed in a single matrix. The working group selected a chair.
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)	Completed Recommendations Document and executive summary in Q3.
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 Q4, target completion, perhaps beyond	Hired a consultant to develop a trainer's guide and training module on the topic of "understanding the clinical research process and principles of clinical research" for CAB members working with HIV clinical trial sites associated with the networks. The consultant has met via conference calls with HANC representatives and working group co-chairs and has been actively reviewing existing community training materials provided by HANC related to the topics above for the purpose of adapting appropriate, high-quality content for use in a cross-network training module.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.	Ongoing throughout year	Held a conference call with DAIDS and CSI representatives to discuss how this group can more effectively collaborate with HANC/CSI/DAIDS and the EMTF. The EMTF will be working with this working group and asking the working group to serve as a resource.
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.	Adequate site-level CAB support.	Ongoing throughout year	Held three conference calls and added new members to the working group, including two members from the DAIDS Office of Clinical Site Oversight. The working group discussed issues regarding site CAB funding and questions regarding how sites determine allocation of resources. The working group will be looking at the OCSO reports from sites regarding CAB funding to make some recommendations and the possibility of a CAB Survey. The working group selected a chair.

Training Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 year	The Committee recommended to have PPD draft a template based on previous training needs assessments created by the networks, create a subcommittee from the training committee and/or those interested in their networks to participate which would review the template and see if there is any redundancy and come up with guidelines on how to prioritize needs that come back once the needs assessment is distributed. It was suggested for different networks needing different things from the assessment that perhaps those topics could be addressed at the network meetings. A training topics blog was also set-up on the portal so on-going information on a topic can be captured in one place.
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.	August 2007-April 2009	Full funding for the supplemental request has been approved. The HRCT WG held one call to review what has been developed to date and provide additional feedback of new materials for the curriculum. Jonathan Fuchs, Ed Wolf, Wayne Wilson met with the contracted eLearning vendor SMI for a 3-day meeting in North Carolina to outline and develop the 8 modules under development for the curriculum. Monthly training of mentor calls follow-up calls have been set-up with the 6 pilot mentors which will continue through August. On-going weekly check-in calls with SMI and the HRCT development team continue as planned.
Objective #3: Develop a modular administrative and fiscal training program.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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
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 throughout year	Two DLMS demos were set-up for the Training Committee. Training representatives are identifying pilot sites for the DLMS. 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 working with the representatives to offer access to trainings during their network meetings such as DAERS, CSM and safety workshops.
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 #2.				
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 #4.				

Site Management & Logistics Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Ongoing throughout year	HANC has had monthly calls with OCSO leadership to facilitate communication with networks and sites about funding deadlines for year 4 and OSCO Director Manizhe Payton joined one of the Network Leaders Group call to discuss these issues. HANC posted OCSO SOPs on the HANC web site.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Ongoing throughout year	HANC conducted every other month calls with OPCRO and OCSO and monthly calls with OCSO to address site management issues. HANC formed a financial disclosure working group in Q3 to attempt to standardize policies and procedures across networks.
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 are ongoing.	Final adherence meeting report disseminated and a new Behavioral Sciences Working Group (BSWG) was formed with support from the NIMH. The BSWG will begin their work in Q4.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 further revised based on feedback from NIAID Office of Technology and Information Systems (OTIS) in Q3. Draft will be shared with OCSO staff and Network Leaders in early Q4 to discuss implementation. IT Best Practices are informing IT training in development by DAIDS staff.
Objective #2: Establish "Input/output transmission Standards" to describe necessary structure for data interchanges of assays, inventories, and manifests.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Harmonize data collection across the networks.	Continuing from work in Year 2; Q2 began more focused effort.	Activity completed.
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. Discussions with DAIDS are ongoing and we hope for resolution in Q4.
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 drafted 5 mini-SMQ AIDS-event queries in order to better review safety data to determine HIV-related events in relation to safety profiles. The working group held 3 calls this quarter. Kathy Huntley has mapped CDC and WHO HIV classification systems and drafted example SMQs for the DMCs and statisticians to consider.
Objective #4: Identify issues and determine how data collection for transgender participants in DAIDS-funded HIV/AIDS clinical trials should be best conducted.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 will resume in Q4 after transgender training is held at the HVTN FGM in May 2009.
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)	In Q3 DAIDS and OTIS staff developed IT training curriculum that will be presented at DAIDS Regional Training events, with the first targeted for the Rio Regional DAIDS Training Event June 1-5, 2009. DMCs reviewed the *Electronic Information Safety for Research* course outline and provided feedback. Before translating the materials and offering the training in Rio, DMC working group members will review the course material (Q4). OTIS revisions were incorporated into the Data Collection module; decision about dissemination anticipated in early Q4.
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); ongoing thereafter.	Objective met: Chris Whalen from OTIS is joining regular DMC Harmonization calls and participating in cross-DMC activities.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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	Weekly calls of the EMTF planning group are ongoing. The Scientific Agenda and Objectives WG held a call this quarter and continues to collect information to inform a detailed analysis plan to address questions generated by the EMTF. Network publications were collected in Q3 and a bibliometric analysis will be conducted in Q4. Network SOPs for publications and results dissemination were collected in Q3. The Communication, Collaboration and Harmonization WG comprised of HANC staff finalized a survey of HANC portal users in Q3 to be distributed in Q4. Community Partner's evaluation subcommittee held a call and will assist on the community and participants working group of the EMTF. The Operations, Policies and Resources WG held a call and are beginning to evaluate data in the DAIDS-ES system and the networks assessing timelines for implementation of protocols and accrual at pluripotent sites.