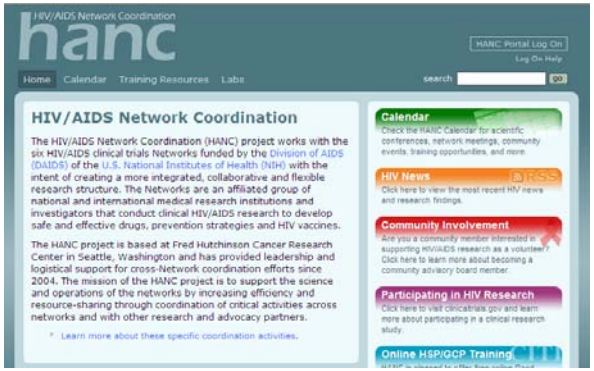
Quarterly Report: Q1 of Year 4, June 2009-August 2009

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
- General announcements
- Network newsletter library

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Review design and flow of the HANC website and reorganize to improve functionality and ease of use.	Improved communication and access to information.	Q2-Q3	This is a new project.

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 37 individuals with HANC portal user accounts, for a total of 596 active HANC Portal user accounts. Two additional team sites were developed this quarter, including the new Communications Working Group and the LFG-DCLOT Collaborative Working Group, for a total of 40 team sites. HANC portal projects for 2009-2010 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Review user statistics and member survey data collected in to inform HANC Portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives.	Ongoing	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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Provision of the DAIDS-ES protocol reports on the HANC portal.	Ready access to all protocol reports including the quick summary data and accrual data from the DAIDS-ES system in real-time for HANC portal users.	Development Completed.	In collaboration with Digital Infuzion, HANC staff created a web feed on the HANC portal allowing users to access DAIDS-ES protocol reports data with a user friendly directly of all protocols. HANC presented this project at the DAIDS-ES All Collaborators Meeting in July 2009. Ongoing activities include embedding links to protocol reports in call minutes and linking to protocols referenced in the HANC newsletter.
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 protocol documents for HANC portal users	Approval from DAIDS received in Q2, should be completed in Q2.	HANC was awaiting approval of request to DAIDS to link the DAIDS-ES document library to the protocol reports available through the HANC portal-DAIDS-ES web feed.
HANC staff	Adding features and resources for HANC members	Improved resource and information sharing amongst HANC members.	Ongoing	Added a library of network newsletters, network meeting agendas, and the "Daily Dose" (a digest of programmatic activities), and expanded the member profile library.

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 Renée Holt, RN, JD, MPH, Regulatory Affairs Manager of the HIV Vaccine Trials Network, discussed the central IRB established for HVTN 505 at the FHCRC. 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 held monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC held monthly calls with OCSO leadership and two calls with OCSO and OPCRO leadership. HANC helped distribute and solicit comments on two draft documents from DAIDS, "Division Of AIDS Table For Grading The Severity Of Adult And Pediatric Adverse Events, Version 1; December, 2004, Clarification July 2009", and the draft of the "Manual for Expedited Reporting of Adverse Events (EAEs) to DAIDS", version 2.0. HANC also worked with the network leadership, the Lab Focus Group and OCSO to assist with dissemination of information about the site infrastructure awards. HANC is continuing to work with OPCRO and the networks to disseminate information about the new ClinicalTrials.gov reporting requirements.

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 laboratory 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.	Distributed two sets of working group updates to the committee.
Lab Focus Group	Develop communication plan for laboratory audits.	Define a clear and consistent communication plan among Network Laboratories, DAIDS and SMILE for timely resolution of audit findings.	Q1 Incorporate feedback from DAIDS; Q2 Incorporate feedback from SMILE and finalize plan.	Incorporated feedback from DAIDS.
LFG-DCLOT Collaborative Working Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for discussion among Network Laboratories and the DAIDS Clinical Oversight Team	Ongoing throughout the year	Developed group membership list and polled for first call time.
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.	Ongoing throughout the year as needed.	Added two pages for the information about viral load platform switches and ordering fetal bovine serum. Corrected VQA datasets information. Added archive of communications sent to labs on behalf of the networks. VQA Reagent Order Form completion is pending further information from the VQA.
HANC Support 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	Updated laboratory contact information using monthly PPD updates, and miscellaneous notifications from labs.
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				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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.	Q1 Send to DAIDS and SMILE for approval; Q2 Finalize and post on public website.	Distributed LFG-approved guidelines to DCLOT and SMILE for review.
Lab Focus Group	Develop guidelines for back-up plans for safety labs.	Consistent quality control of safety testing at Network-affiliated laboratories and back-up labs.	Q1 Draft plan, review within LFG and send to SMILE and DAIDS for review; Q2 Incorporate feedback from SMILE and DAIDS and finalize plan.	Drafted plan, reviewed within LFG and sent to SMILE and DAIDS for review.
IQA CD4 Working Group	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA 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 11 labs were discussed and resolved. Initiated development of back-up plans for CD4 Labs Initiated discussion of CD4 lab validation
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 10)	Held 2 calls, the focus of which was the development of program criteria. Continued development of ICAG guidelines
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.	Lab performance was not reviewed on ICAG calls during Q1.
ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository	Reliable results in functional and phenotypic assays.	Q1 Develop algorithm for selecting samples at BRI for QC; Q2 Initiate pilot testing of incoming samples and testing of samples at BRI	Initiated development of algorithm for selecting samples at BRI.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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 5 calls during which the CPQA working groups communicated program details to relevant parties and reviewed: • AVR SOP Review Process • CPQA Program By-Laws • PT Program Guidelines • CPQA Request Policy • Training options and plans • Changes to the CPQA website and LDMS • Prequalification/troubleshooting panels • Changes from HPLC to UPLC • Lab QC • Audit readiness
Virology Quality Assurance Advisory Board (VQAAB)	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 the group reviewed proficiency testing reports and cumulative performance summaries and discussed: • RNA accuracy data • Controls for new viral load platforms • Need for continued use of DNA blinds • LDMS reporting • Validation of FBS lots
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	Update Lab Process Chart (LPC) standard wording and format.	Improve design of LPC for efficiency and user-friendliness and update standard wording to reflect current practice.	Q1 Divide LPC into sections and assign primary editors to each section; Q2 Complete updates to standard wording; Q3-4 Reformat LPC	Divided LPC into sections and assigned primary editors Initiated revisions to standard wording

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
ACTG IMPAACT/LTC and HANC Support Staff	Add comments and example reference documents to PBMC Lab Audit Shell.	Provide laboratories with guidelines for audit readiness.	Q1 Divide shell into sections and assign primary editors to each section; Q2 Complete comments and resources.	Divided shells into sections and assigned primary editors Initiated drafting of comments and compilation of resources
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.	Q1 Supervise installation of instruments at priority sites; Q2 Complete installation	Held 2 calls with Abbott to review status of implementation and provide information and guidance Sent update memo to labs
PBMC SOP Implementation Working Group	Develop and implement a cross-network/CHAVI PBMC Processing SOP.	Consistent PBMC processing at network and CHAVI labs.	Q1 Revise SOP, post version 2 on HANC public website, translate SOP into Spanish, French, Portuguese and Thai	Version 2 of SOP and reference document posted Spanish, French and Portuguese translations of SOP posted Thai translation pending corrected formatting
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	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 3 labs in South Africa and Botswana for July, 2009. Planned site visit in Thailand for Jan., 2010. Held 1 call to review TB lab protocol readiness.
TB Diagnostics Working Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for communication among the networks, SMILE and DAIDS regarding TB laboratories and diagnostics.	Ongoing throughout the year.	Held 1 call to review: • Site visit reports and plans • PPD audit shell for TB/AFB labs • CDRC application • Guidelines for specimen transport
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 Draft specimen collection and transport into the guidelines; Q2-4 Incorporate alternative EQA methods and collection and transport guidelines into document.	Drafted specimen collection and transport guidelines and presented to ACTG/IMPAACT LTC for review and feedback.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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 Q2 (Dec 09)	Held 3 calls to review data and preliminary analyses.

Behavioral Science Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science.				
Behavioral Science Working Group	Propose Behavioral Science plenaries to network conference planning committees. Curate and organize sessions.	Identify network and behavioral science agendas/priorities and identify gaps, overlaps and provide input from the behavioral science perspective in shaping agenda items	Ongoing	Helped coordinate the "Integration of prevention and therapeutic HIV research: opportunities and challenges" symposium at the June 2009 ACTG Full Group Meeting. The BSWG will continue to propose topics for network meetings.
Objective #2: Create a repository of behavioral science tools and measures.				
Behavioral Science Working Group, NIMH	Create a library on the HANC portal for all BSWG members to access "state of the science" measures, forms, and articles.	Allow investigators to compare efficacy of research tools and share outcomes of behavioral science substudies/practices in network clinical trials.	Ongoing	The library has been completed and is updated as able.
Objective #3: Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings and workshops.				
Behavioral Science Working Group, NIMH	Provide opportunity for investigators to share ideas and collaborate on behavioral science materials and recommendations.	Ensure that the best quality behavioral science is integrated into clinical trials	Ongoing	Discussed developing a white paper on prevention adherence in HIV clinical trials with the Forum for Collaborative HIV Research

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #4: 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 face-to-face meeting with cross-network representatives.	Explore HIV/AIDS related behavioral science research and apply them to network clinical trials.	TBD	Discussed possible meeting topics.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop a community research priorities agenda.				
Community Partners Research 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.	Identify network and community scientific agendas/priorities and identify gaps, overlaps and provide input from the community perspective into the research agenda.	Q4, target completion, perhaps beyond	With the selection of a new chair, the group held three conference calls and developed a matrix template with all the research priorities. The working group reviewed the various network priorities and decided to divide the priorities between prevention and treatment. The group is working on the best format to display the priorities and highlight overlaps and gaps in the research agendas.
Objective #2: 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	Held multiple conference calls with consultant and working group chair and working group members to review and provide edits to DRAFT participant and instructor's guide and training module slide set 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 working group solicited comments and feedback from subject matter experts on the DRAFT materials and initiated discussions regarding distribution of documents once finalized.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact and serve as an advisory group to the EMTF.				
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	In addition to holding three conference calls the group held a conference call with DAIDS and CSI representatives and discussed expectations of this group and how this group can more effectively collaborate with HANC/CSI/DAIDS and the EMTF to be more effective. Members were actively recruited to serve on the EMTF Community and Participants Advisory Group to work with and assist in guiding the EMTF's evaluation efforts. The working group solicited evaluation tools from all the networks in addition to developing a matrix to organize the network responses. The group determined that once the responses have been organized and discussed they would update the EMTF on their progress.
Objective #4: 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 created a DRAFT survey to determine how informed CAB members and site staff are of support available to CABS and allocation of resources. Working group members discussed the importance of refining survey questions to solicit appropriate and meaningful data. The working group queried network site staff for a list of CABs prior to sending out survey. The working group decided to solicit input from HANC and perhaps CSI to assist in survey refinement and administration.
Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming Network recompetition and restructuring process.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Community Partners	Solicit input from networks and other interested groups to provide input and recommendations to DAIDS regarding the Network recompetition and restructuring process.	Identify network and community concerns and provide input in shaping the DAIDS recompetition and restructuring process.	Ongoing throughout year	Held discussions with CP Chairs, CP Executive Committee and CP regarding the role of CP in soliciting input.
Objective #6: Utilize CP to provide input and recommendations to ensure that the HANC cross-network Legacy Project achieves increased inclusion of African-American and Latinos/Latinas in HIV prevention and therapeutics research.				
Community Partners	Work closely with the HANC cross-network Legacy Project to identify and address common issues relating to community involvement.	CP reps will serve on the HANC Legacy Project Work Group and collaborate in consultation with the CP Executive Committee and related working groups.	Ongoing throughout year	Held discussions with CP Chairs, CP Executive Committee and CP regarding the role of CP in soliciting input.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop a cross-network contact list				
Communications Working Group	Create a cross-network contact list for staff reference.	Identify network counterparts and facilitate communication amongst network staff.	To be completed in Q2	Created cross-network contact list on HANC portal. The list will be posted on the HANC portal and announced in the HANC newsletter. Updates will be provided on a quarterly basis.
Objective #2: Develop a network newsletter library				
Communications Working Group	Create a network newsletter library on HANC portal and public sites.	Share network news and activities	Completed	Objective achieved. HANC staff developed a reference library on the HANC portal and duplicate library on the public site. The code is designed to filter out HANC-member only newsletters when publishing to the public site.
Objective #3: Share communications tools and experiences				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Communications Working Group	Establish monthly conference call schedule and determine topics of interest.	Share industry best practices, resources, recruitment tools, and study results dissemination experiences.	Completed	Shared focus group outcomes, results disseminate plans, and initiated presentation series considering "Novel Communications Technologies Employed in DAIDS Clinical Trials". The group has considered Twitter and will review Facebook and discussed the merits of instant messaging programs.

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 year	PPD is finalizing a draft template based on previous training needs assessments created by the networks. Template to be discussed and reviewed in Q2 by a subcommittee from the training committee and/or those interested in their networks to participate. Two additional training needs have been identified which include informed consent with vulnerable populations and a refresher training on source documents/essential documents. A need for an online reference guide regarding all DAIDS ES applications and specific trainings for each was also recommended to be created. HANC and DAIDS are working together to address these needs. The DAIDS Learning Management System (DLMS) became available for all sites to use and is regularly updating and adding training as requested by the networks. HANC has worked closely with CITI and PPD to make all of CITIs trainings easily accessible and complete. PPD is also working towards creating an interface with CITI so users can use the same password when logging onto the DLMS and CITI.
Objective #2: Continue the development of core training materials addressing risk reduction counseling in biomedical prevention and treatment trials.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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-TBD	Extensive review and editing of the Training Resource Manual, HRCT study guide, 8 eLearning modules was completed. Go-sessions with the 6 South African pilot sites were held to preview the various components of the pilot before launch. 72 South Africa pilot trainees from the 6 pilot sites were set-up for the first phase of the pilot roll-out which was to complete a pre-vignette. All contact information for each site was compiled. Monthly training of mentor calls have continued with the 6 pilot mentors. On-going biweekly check-in calls with SMI and the HRCT development team continue as planned. Monthly HRCT Executive Committee calls continue as planned.
Objective #3: Develop a modular administrative and fiscal training program that supplements NIAIDs Grants Policy and Management Training.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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	PPD moved ahead with the pending CRS Task request and did a gap analysis of the DEA Grants Management on-line training and the cross-network Admin-Fiscal training objectives. PPD reviewed the gap analysis report with the Committee. The majority of objectives the Admin-Fiscal WG developed were met in the DEA's training program. It was recommended to have the Admin-Fiscal WG review the document and provide feedback as to whether or not we should develop additional modules to meet the objectives where we have unmet needs. Christie distributed the gap analysis and compiled comments provided from the Admin-Fiscal WG. OCSO is also currently reviewing the document. All comments are currently under review by HANC and DAIDS. These comments may be brought to the DEA to see if they are willing to do enhancements to their current training or have the CRS Task Request develop modules as needed.
Objective #4: 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 #3.				

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.	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.
Objective #2: Work closely with network staff and DAIDS officers to harmonize network Conflict of Interest/Financial Disclosure requirements, synchronize network financial disclosure reporting schedules, and develop a cross-network web-based reporting interface, pending availability of funds for the latter effort.				
Network staff, OPCRO and OCSO	Develop a cross-network SOP addressing Financial Disclosure reporting requirements.	Harmonize the collection of financial disclosure data across the networks for their benefit and that of site investigators.	Ongoing throughout year	HANC has had monthly calls with network and DAIDS reps to prepare a draft SOP for network review committee and DAIDS consideration. Draft SOP was submitted to constituents in August and the WG is awaiting feedback.
Objective #3: 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.
Objective #4: Investigate the feasibility of the establishment of a centralized IRB review process for network protocols.				
Network Leaders	Review the experience of the HVTN in establishing a central IRB for HVTN 505.	Address potential utility, costs and benefits of centralized IRBs.	Q1	Renée Holt, RN, JD, MPH, Regulatory Affairs Manager of the HIV Vaccine Trials Network. discussed the HVTN's experience establishing a centralized IRB at the FHCRC on the July 2009 NLOG call. Based on that experience the other networks did not express enthusiasm for establishing central IRBs at this time.

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.	Review and updates ongoing.	Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. IT Best Practices are informing IT training in development by DAIDS staff.
Objective #2: 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.	Discussions with DAIDS are ongoing and we hope for resolution in Q2.
Objective #3: 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 will resume in Q2.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #4: 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.	Ongoing	Standing opportunity for DAIDS staff to address DMC training-related concerns. Ongoing discussion of DAIDS Learning Management System (DAIDS LMS) training at DRTEs.
Objective #5: Harmonize MedDRA coding for AIDS Defining Events				
AIDS Defining Events Working Group	Reconcile CDC and WHO diagnostic classifications with MedDRA codes	Realize DAIDS mandate to use MedDRA codes in DAIDS-funded clinical trials	Ongoing. Expect resolution in Q2	Mappings have been completed. DAIDS MedDRA consultant, Kathy Huntley, is upversioning the documents and developing a MedDRA guide for reviewers. SDAC coders are running beta tests with mappings and WG is preparing to submit mappings for clinical review.
Objective #6: Implement ClinicalTrials.gov results reporting requirements.				
DMC Harmonization Working Group	Implement new reporting requirements. Clarify responsibilities of DMCs and networks.	Minimize impact of changes in reporting though preparation and sharing concerns with DAIDS leadership.	Ongoing	HANC staff disseminated draft policies to DMC WG and provided opportunity for DMCs to discuss issues on monthly calls. HANC shared network and DMC feedback to DAIDS.
Objective #7: Develop a "DAIDS Contacts FAQ" for data management-related issues.				
DMC Harmonization Working Group	Develop a contact list for DMC-related areas within DAIDS	Allow DMC staff to contact the appropriate DAIDS contact, to facilitate conversation, and expedite resolution of questions.	Begin work in Q1 (Aug 09)	DMCWG has reviewed a draft FAQ. HANC will submit to OPCRO and OCSO in Q2 (Oct 09).
Objective #8: Harmonize Clinical Event Collection policies and procedures to make recommendations on Adverse Events Reporting.				
DMC Harmonization Working Group	Coordinate and harmonize ongoing activities at DAIDS and the networks around clinical event data collection and adverse event reporting.	Create consistent policies and procedures for clinical event data collection nd adverse event reporting.	Ongoing	This objective is addressed in ongoing calls with OPCRO and the DMC Harmonization Working Group. HANC is assisting in Q2 with collating comments on the DAIDS revised Manual for EAE reporting.
Objective #9: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS).				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
DMC Harmonization Working Group	Provide DMC perspective and feedback to DAERS program staff and DAIDS leadership	Ensure DMC systems are considered in the development and implementation of policies relating to DAERS.	Ongoing	Opportunity to discuss experiences using DAERS on monthly and ad hoc conference calls.
Objective #10: Facilitate cross-network Appendix Merger Project Working Group				
Cross-network Appendix Merger Project Working Group	Review clinical and coding recommendations from a cross-network perspective	Reconcile ACTG/IMPAACT diagnostic code appendices 40, 50, and 60 and merge into one appendix.	TBD	Awaiting clinical and coding recommendations based on clinician review.
Objective #11: Develop a Serious Adverse Events/Expedited Adverse Events Reconciliation Policy				
DMC Harmonization Working Group, OPCRO, RCC	Develop a cross-DMC SAE/EAE Reconciliation policy	Standardize SAE/EAE Reconciliation reporting procedures.	Complete policy in early Q2	Developed draft policy in consultation with reps from RCC and Safety and Pharmacovigilance Team. Policy to be reviewed by OPCRO in October 2009. Next steps pending OPCRO feedback.

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	Hold monthly calls with each working group and CSI to advance the development of an evaluation system.	Develop evaluation metrics and processes to evaluate DAIDS and Network success and identify opportunities for improvement.	Ongoing	Calls with the EMTF planning group are ongoing every other week. The Scientific Agenda and Objectives Advisory Group has completed an Initial bibliometric analysis and secondary analyses are ongoing. One call was held this quarter to discuss preliminary data. The protocol implementation timeline review is ongoing as is collection of accrual data for pluripotent sites compared to single-network affiliated sites in the Operations, Policy and Resources Advisory Group. They have held one call during Q1 to discuss this data.

HANC Cross-Network Legacy Project Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop supplement proposal for a HANC cross-network Legacy Project.				
Legacy Project Leadership Team	Draft a proposal for supplemental funding for a HANC cross-network Legacy Project detailing the project scope, intent, timeline and criteria to determine project success.	Enhanced cultural competency within the networks and build relationships of trust with African-American and Latino communities within the U.S. to enhance participation of African-Americans, Latinos, and Latinas in network trials.	Completed proposal and submitted in Q1.	Proposal submitted in August and supplemental award notice was received in September.
Objective #2: Develop an effective and efficient transition strategy from HVTN Legacy Project activities to HANC cross-network Legacy Project activities with clear definitions of synergy and cohesion while still maintaining a clear distinction between the two projects.				
Legacy Project Leadership Team	Develop a transition plan to allow the HVTN Legacy Project and the HANC cross-network Legacy Project to work collaboratively and seamlessly with each other and collaborators.	Develop both a collaboration and distinction between the HVTN Legacy Project and the HANC cross-network Legacy Project.	Began meetings in Q1, ongoing in Q2.	Regular meetings were held with HVTN Legacy Project and HANC to discuss the new HANC cross-network Legacy Project and its relationship with the HVTN Legacy Project.