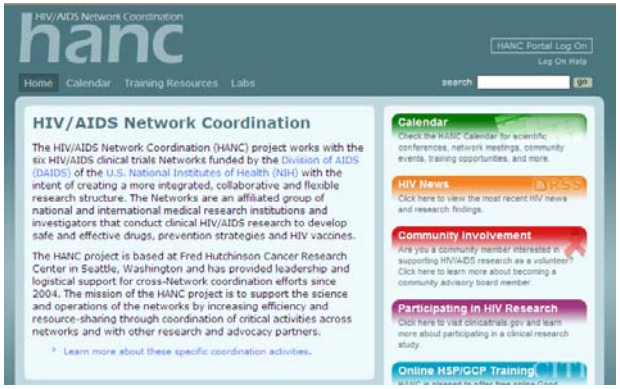
Quarterly Report: Q3 of Year 4, December 2009-February 2010

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:

- OCSO SOPs
- Pages for the DAIDS-ES Applications Training Information

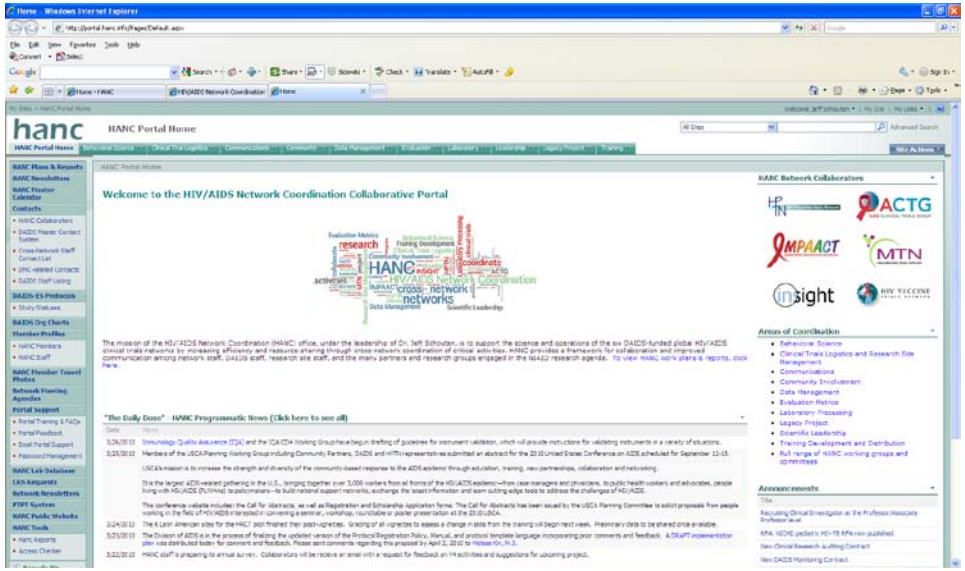


Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
HANC staff	Review design and flow of the HANC website and reorganize to improve functionality and ease of use.	Improved communication and access to information.	Q2-Q3	Updated Training Resources page. Continued updates to access detailed information for DAIDS-ES applications which includes DAERS, Clinical Site Monitoring and Protocol Registration.
HANC & IT staff	Public site redesign and rebranding project	Improved capacity, ease of navigation flow and access to information.	Q3-Q4	Began redesign of logo and drafted plan to revise the site structure.

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 61 individuals with HANC portal user accounts, for a total of 794 active HANC Portal user accounts. Three additional team sites were developed this quarter, including the new Communications Resource Center, the AIDS Defining Events Clinical Review site, and the Site Coordinators team site for a total of 47 team sites. HANC portal projects for 2009-2010 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
HANC staff	Review user statistics and member survey data collected 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 the portal. HANC staff reviews usage reports on an ongoing basis.
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.	Ongoing activities include embedding links to protocol reports in call minutes, linking to protocols referenced in the HANC newsletter, and updating the protocol report details as necessary.
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.	Q4.	HANC received approval to link the DAIDS-ES document library to the protocol reports available through the HANC portal-DAIDS-ES web feed. Connectivity was tested in the sandbox in February 2010. Service will be initiated with the DAIDS-ES upgrade in April 2010.
HANC staff	Adding features and resources for HANC members.	Improved resource and information sharing amongst HANC members.	Ongoing.	Expanded the member profile library, and reorganized the portal homepage.
HANC and IT staff	Created two new order forms and order management systems for Virology Quality Assurance (VQA).	Expand the number items the VQA can offer to its customers and improve order management efficiency.	Q2 Development new order forms; Q3 Complete form libraries and launch.	Launched new order forms and form libraries.



Social Networking & Information Sharing

HANC has established Twitter (search for "Hancprograms") and Facebook (search for "Hanc Programs") accounts to share general programmatic updates with a broader audience. Due to the interest in the resources shared in the HANC newsletter, HANC staff has increased the publication frequency from quarterly to bi-monthly. "HANC Portal 101s" are now offered on a bi-monthly basis. HANC members are invited by HANC to participate in a walk-through of portal/website resources and given the opportunity to learn more about SharePoint technology. In Q3, HANC hosted a cross-network call to discuss network IT infrastructures. The conversation focused on network challenges, information-sharing practices, and possible areas for collaboration and harmonization. HANC expects to hold a series of follow-up calls to address these matters.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) did not have a call this quarter due to the January meeting of the Strategic Working Group (SWG). The SWG met in Bethesda, MD on January 27-28, 2010. The MTN and INSIGHT networks presented network updates and the HPTN presented an update on HPTN 065 – the "Test and Link to Care-+" Protocol. HANC organized 3 focused monthly conference calls with the six Network Principal Investigators and Co-PIs 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 did not have any monthly calls with OCSO leadership due to scheduling conflicts, but HANC was in frequent contact with OCSO to distribute policies in development to the Network Leadership Group. OCSO representatives attended a Data Management Harmonization Working Group call and 2 Network Leadership Group calls to discuss OCSO policies and procedures. HANC held one call with OCSO and OPCRO leadership during which OPCRO presented updates on the DAIDS EAE Reporting Manual Version 2.0 and implementation plans and timeline; ClinicalTrials.gov reporting; status of the EAE/SAE reconciliation policy draft document; modified site monitoring protocol intensity process; and a new protocol registration system. OSCO presented updates on the report of site funding for support of community activities; a new site monitoring plan; and the SOP for Temporary Suspension of Clinical Research Site Activities. HANC continued to work with OPCRO on the draft of the "Manual for Expedited Reporting of Adverse Events (EAEs) to DAIDS", version 2.0 and the proposed implementation plans. HANC also continued to work with OPCRO and the networks and disseminated information about the new ClinicalTrials.gov results reporting requirements, and the resultant shift in responsibility to the networks for studies for which DAIDS is not the IND holder.

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 laboratory programs.				
ACTG/IMPAACT LTC and HANC Support Staff	Develop and maintain a Lab Tech (LT) Committee Workload Tracking System.	Track information about LT work assignments to ensure equitable sharing of responsibilities.	Q2 Develop and launch; Q3 Expand reporting capabilities; maintain throughout the year.	LT Workload Tracking System updated with current information in an ongoing manner and used to generate network reports.
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 one set of working group updates to the committee. • Held one conference call to review CPQA program
Lab Focus Group/LFG-DCLOT Collaborative Working Group	Determine process for vetting new labs.	Minimize unnecessary additions of new labs to DAIDS system, thereby minimizing resources necessary for lab start-up and monitoring.	Q2 Collect information; Q3 determine process.	Determined that the best way to vet new labs would be on an ad hoc basis.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Lab Focus Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion and resolution of issues that affect multiple networks.	Ongoing	Held 6 calls during which the group: • Discussed how best to meet the needs of TB diagnostics labs that require more information to meet GCLP requirements. • Discussed distribution of informational memo about the DAIDS Learning Management System (DLMS) to labs. • Initiated review of new online GCLP training. • Initiated development of CRS request for LDMS training resources. • Determined group goals for coming year
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.	Held two conference calls, during which the group: • Resolved how to best treat analytical study plans in audit shell. • Discussed validation of rapid tests • Finalized the guidelines for the development of back-up plans for safety testing labs • Discussed the limitation of new testing sites • Discussed oversight of non-US CD4 labs • Finalized the Safety Guidelines for Total Quality Management • Were updated on the status of online GCLP training
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.	Regularly updated page about ordering fetal bovine serum.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Ongoing.	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.				
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; Q3 finalize and post on public website.	Finalized and posted on public website.
Lab Focus Group/LFG-DCLOT Coll. WG	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; Q3 finalize plan.	Finalized and posted on public website.
Lab Focus Group	Establish oversight of U.S. CD4 laboratories.	Ensure standard quality assurance for CD4 testing in the U.S. for network protocols.	Q2 Collect information about how U.S. CD4 laboratories are currently overseen by the networks; Q3 Collect information about IQA CD4 program in the U.S.; Q4 Establish mechanisms for network oversight of U.S. CD4 proficiency testing results and incorporate into TQM.	Received presentation of overview of IQA CD4 proficiency testing program.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Held three calls during which: • Testing issues at labs were discussed and resolved. • Development of back-up plans for CD4 labs was continued. • Effectiveness of tracking and communication tools was reviewed. • Comparison data between instruments was reviewed • Training needs were clarified
IQA Cryopreservation Proficiency Testing Advisory Group (ICAG)	Develop IQA intervention, corrective action, remediation and training approach;	Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories.	Completion target Q4 (May 10).	Held three calls, during which: • Comprehensive program criteria were completed • Back-up laboratory options were considered • Revision of reminder notice memo was initiated
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.	Proficiency testing summary was reviewed and specific laboratory issues were resolved.
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.	• Determined that quality control of existing samples at BRI isn't feasible • Pilot testing of incoming samples in progress

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
ICAG	Formulate communication scheme and document (ICAG Working Group Guidelines for Communication and Data Flow) as part of the TQM document.	Clarify and outline responsibilities, monitoring, data and communication flow within the IQA PBMC Cryo PT program as part of the TQM document.	Q3 and 4 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: • Recommendations for HIV RNA processing time • AVR/SOP submissions • Validation of methods in rare matrices • Training options and plans • CPQA Program By-Laws • Advisory Board membership • Assay validation • Use of dried blood spots • Changes to the CPQA website and LDMS.
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: • Resistant estimators of the Poisson parameter for HIV GEN proficiency testing • External controls for the Abbott HIV RNA assay and implementation plan • HIV GEN Data Outlier Tool
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.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 initiate updates to standard wording; Q3 complete updates to standard wording; Q4 reformat LPC.	Continued revisions to standard wording.
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 compile comments and resources; Q3 finalize.	Continued compilation of revised sections of audit shell and resources.
Lab Focus Group	Provide estimates of needed Roche kits to Roche.	Ensure adequate supplied of kits for network protocols that would otherwise be discontinued.	Q2 Determine Roche requirements; Q3 complete estimates	• Held 1 call with representative of Roche to clarify details of kit obsolescence and resolve other Roche kit issues. • Finalized estimates of 2010 CAP/CA Roche kits and initiated estimates of five other kit types.
Lab Focus Group	Recommend and implement new real-time viral load assay for use in network protocols with viral load primary endpoints.	Ensure reliable and consistent data collection.	Q1 Supervise installation of instruments at priority sites; Q2-3 Conduct installation, validation and training. Q4 Complete installation, validation and training.	Held 1 calls with Abbott to review status of implementation and provide information and guidance; status of installation pending.
Lab Focus Group	Develop common policies and tools for tracking PBMC processing time.	Reduce confusion and increase efficiency at labs; increase overall quality of PBMC specimens.	Q3 Initiate discussions; Q4 Finalize policies and tools and send communicate to labs.	Clarified common expectations for PBMC processing time and potential consequences/follow-up when required processing time is exceeded.
Lab Focus Group	Develop cross-network approach to marking critical items on action plans.	Increase focus on truly critical items on action plans; increase efficiency of lab responses.	Q3 Complete	Determined that the truly critical items are those that affect patient safety and/or study outcomes.
Lab Focus Group/ VQAAB	Clarify HIV RNA processing time limits and communicate them to labs.	Reduce confusion and increase efficiency at labs; increase overall quality of HIV RNA specimens.	Q3 Complete	Completed

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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	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.	Held three calls to discuss: • Site visit reports and plans • Regional meeting of TB lab personnel in Africa • Validation of MicroBank tubes • Point-of-Care (POC) workshop at ACTG Leadership Meeting • Query for capabilities of US labs • Status of laboratory EQA • Overview of POC status
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.	• Reviewed site visits reports from labs in Kenya, Zambia and Zimbabwe, Thailand, Zimbabwe, Botswana and Malawi
TB Diagnostics Working Group	Assess capabilities of TB diagnostics labs in the US.	Evaluate TB diagnostics labs for capacity to participate in network protocols.	Q3 Design and launch survey; Q4 Compile, analyze and review survey results.	Designed and launched survey.
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.	On hold in Year 4.	This project is on hold.

Behavioral Science Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 plenary sessions 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.	The BSWG will continue to propose topics for network meetings. The group discussed the possibility of hosting symposia at the Spring 2010 ACTG and/or HPTN/IMPAACT conferences.
Objective #2: Create a repository of behavioral science tools and measures.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 created and is updated as able. Renamed titles for ease of use and solicited network adherence measures.
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. The Working Group discussed ongoing network behavioral and social science activities. HANC is compiling a list of network-affiliated behavioral and social scientists and will create a "Behavioral Science Interest Group" distribution list modeled on the NLOG. The list will allow investigators to share updates in the field, innovative research methods, and links to seminal papers.
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, F2F Steering Committee	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.	Q4.	The Steering Committee met once a month to discuss the meeting agenda, speakers, and attendees. HANC staff has secured meeting space and hotel rooms.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 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.	The group held three conference calls and compiled a list of the various network research priorities and examined the list to determine what category or categories would fit a particular priority. Based on that compilation, the Working Group developed a priorities continuum addressing various research priorities.. The group is working on the best format to display the priorities and highlight overlaps and gaps in the networks' research agendas. The group is also in the process of discussing how best to present these priorities to the full CP during the CP F2F Meeting in May 2010.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 describing Community Partners as well as 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.	Q4, target completion, perhaps beyond.	In partnership with HANC this group submitted a CRS request for a train the trainer session of the newly developed curriculum to be conducted at the DAIDS Regional Training Event in Pune, India in May 2010 to train the site staff and offer the course at their sites for their community members and new site staff. The CRS request was funded and this working group has been working with DAIDS and the local Pune sites to translate the training materials and organize the materials for the DRTE session on May 15, 2010.
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.	Held a joint conference call with the Site-Level Funding work group to revise and enhance survey questions and collaborate with that working group to be more effective. The group provided an update the EMTF on their progress and incorporated feedback from EMTF into the survey questions.
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.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	The working group held a joint conference call with the Evaluation Working Group and worked together to enhance the Evaluation and Site-Level Funding survey questions. Solicited input from HANC, the network liaisons, EMTF and 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.				
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.	Held three conference calls and elected a new CP Co-Chair. Decided to hold a second F2F Meeting in May 2010 to discuss the future role and organization of CP. Formed a F2F Planning Subcommittee which is working on an agenda and the logistics for the F2F Planning Meeting.
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.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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. Three CP members agreed to serve on the HANC Legacy Project Working Group.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Completed initial contact list.	Posted cross-network contact list on HANC portal. 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 Q3
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.	Discussed the influence of and how to respond to blogs. The group considered the RV144 communications plan with invited guests Lisa Reilly of MHRP and science writer Jon Cohen. Reilly has since agreed to join the Working Group. HANC created a "Communications Resource Center" on the HANC portal and will begin creating a library of resources and tools. HANC staff completed one-on-one interviews with Working Group members and is incorporating feedback into call discussions. HANC proposed a Cross-Network "Communications Symposium" to be held in Q4. Planning is under way.

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.	The training needs assessment tool was presented by PPD and reviewed by the Training Committee in January. Demonstrations were offered to the networks to preview with staff. Questions on how the tool and the DLMS can be used to complement one another occurred in February and will continue in March. The training reps shared informed consent processes and techniques sites currently utilize. Materials available were posted to their team site. DAIDS offered training and information sessions at all upcoming network meetings which could include DAIDS ES applications, EAE manual updates and safety training.
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-TBD.	The pilot training for the 6 South African sites was completed. These sites have two most follow-up vignettes planned. Pilot training for the 6 Latin American pilot sites was launched. 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. A F2F meeting was held in San Francisco at the end of January to expand this curriculum to include two additional modules on adherence and couples counseling.
Objective #3: Develop a modular administrative and fiscal training program that supplements NIAID's Grants Policy and Management Training.				

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.	Completed in Q2.	
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 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 regular communication with OCSO leadership to facilitate communication with networks and sites about OCSO policies and OSCO Director Manizhe Payton joined two of the Network Leaders Group call to discuss an OCSO initiative regarding Monitoring Recent Data and other OSCO policies in development.. 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.	HANC has had monthly calls with network and DAIDS reps to prepare a draft SOP for network review committee and DAIDS consideration. The final draft has been prepared and the group is preparing to send to Network Leaders and DAIDS. Implementation is expected by Q4.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	HANC conducted one call with OPCRO and OCSO and no monthly calls with OCSO due to scheduling conflicts. However, HANC had frequent communication with OCSO to share policies in development and information with the Network Leadership Group and the Data Management Harmonization WG. The Site Coordinators Working Group was formed and held their first meeting in February 2010. This group provides a new forum for communication and harmonization of network and DAIDS policies at the site level.
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.
Objective #5: Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks.				
Cross-Network Site Coordinator working group	Provide a discussion forum dedicated to addressing significant issues common across the networks that need to be addressed.	To address issues of common concern and harmonize policies and procedures regarding site-level operations.	Ongoing.	This Working Group held their first call in February. Preliminary issues discussed on the call will be discussed with Network Leadership and DAIDS. Site concerns discussed on the first call were shared with the Network Leadership Group on their February 2010 call. Objectives for the WG will be outlined in March.

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.	Review and updating ongoing.	Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. IT Best Practices are informing IT training in development by DAIDS staff. Review planned for early Q4.
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.
Objective #3: 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. HANC has contacted HVTN staff to determine how best to move forward in a cross-network fashion.
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. Invited DAIDS staff to join calls and discuss training needs resulting from the EAE Manual revisions.
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 Q3.	Mappings have been completed and up-versioned to the current MedDRA standard. SDAC coders are running beta tests with mappings and HANC staff has coordinated a review with DAIDS-affiliated clinicians.
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.
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.	Completed.	DMCWG, OPCRO, and OCSO contributed to a Contacts FAQ. The FAQ is posted on the portal and was announced in the HANC newsletter.
Objective #8: Harmonize Clinical Event Collection policies and procedures to make recommendations on Adverse Events Reporting.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 and adverse event reporting.	Ongoing.	This objective is addressed in ongoing calls with OPCRO and the DMC Harmonization Working Group. The WG discussed proposed changes to the DAIDS EAE Manual on monthly calls. HANC disseminated DAIDS-issued memos.
Objective #9: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS).				
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. HANC will organize a call with the DAERS product champion in Q4.
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; i.e., Appendix 100.	TBD.	Awaiting clinical and coding recommendations based on clinician review. Sent project update to WG members.
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.	Ongoing.	Developed draft policy in consultation with representatives from RCC and Safety and Pharmacovigilance Team. Policy is under review by OPCRO. Next steps pending OPCRO feedback.

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.				
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. Community Partner's Evaluation and Site-Level Funding Subcommittees convened and will assist on the Community and Participants Working Group of the EMTF in developing and distributing a survey to site staff and CABs in March 2010, with the results presented at the CP F2F meeting in May 2010. 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. Manuscripts are being drafted on the bibliometric analysis and protocol timeline implementation analysis.

HANC Cross-Network Legacy Project Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #1: Develop HANC cross-network Legacy Project.				
Legacy Project Leadership Team	Develop a HANC cross-network Legacy Project including 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.	Ongoing.	Proposal submitted in August 2009 and supplemental award notice was received in September 2009. Progress in Q3 included the hiring of 2 Community Engagement Officers and the continued searching for Legacy Project Scientific Director. Also work began to develop the strategic plan for the HANC Legacy Project.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #2: Continue implementation of the Legacy Project transition strategy across the DAIDS-funded networks to ensure activities build upon and include HVTN focused Legacy Project activities and the cross-network expanded activities.				
Legacy Project Leadership Team	Continue with transition planning.	Ensure collaboration with the HVTN Legacy Project and the HANC cross-network Legacy Project.	Began meetings in Q1, ongoing in Q3. Expected full transition by end of Q4.	Regular meetings were held with HVTN Community Relations and Education Unit and Legacy Project to continue planning the cross-network expansion of the Legacy Project.
Objective #3: Continue to establish and implement clear definitions of synergy and cohesion between Legacy Project activities within the HVTN and HANC to ensure coordinated fiscal operations and maintain programmatic distinction while also ensuring singleness among external partners and collaborators.				
Legacy Project Leadership Team	Develop definitions and expectations.	Clear distinction but also coordination of programmatic activities to assure efficient implementation of both HVTN and the expanded network activities.	Ongoing.	Regular meetings were held with HVTN Community Relations and Education Unit and Legacy Project to coordinate the cross-network expansion.
Objective #4: Expand the current Legacy Project Working Group (LPWG) to include membership and participation of all DAIDS-funded Networks and establish regular communications with the working group.				
Legacy Project Working Group	Invite at least 2 representatives from each of the 6 DAIDS-funded clinical trials networks to join the current LPWG.	Ensure inclusion of each network's priorities and establish an efficient linkage between the Legacy Project and each of the Networks.	Began in Q1, ongoing in Q3, completion in Q4.	Expanded network representation on the LPWG includes: ACTG, HPTN, MTN, and INSIGHT. Representation from the HVTN remained the same.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #5: Establish effective and efficient operating systems for the LPWG via Subcommittees.				
Legacy Project Working Group	Establish and maintain LPWG Subcommittees; Vaccine Working Group, Communications Working Group, and the Behavioral Social Science Core. The Long Range Planning Task Force, which focuses on cohesive long range planning, which was previously established, continues its work.	Provide effective operations support for Legacy Project activities with maximum support for and from LPWG representatives.	Ongoing.	Subcommittees were formed and populated with members from the working group.
Objective #6: Establish a cross-network advisory group, the Legacy Project Women's Caucus, composed of women leaders from around the country who represent low-income women, high risk women, women who are living in high risk populations, or women experienced working with these populations.				
Legacy Project Women's Caucus	Establish the Legacy Project Women's Caucus. The Legacy Women's Caucus operates as an integral part of US domestic HIV prevention and therapeutic research effort, focusing on women, especially those living in low-income, high risk areas, and other at risk women.	The Legacy Women's Caucus will operate as an advisory and collaborative entity to the Legacy Project providing important direction and guidance from the perspective of at-risk women and their representatives to the DAIDS HIV clinical research effort.	The selection process began in Q3 with a projected population of the group in early Q4. An inaugural face-face meeting is planned for Q4.	Legacy Project staff has worked with other key leadership (member from HPTN community education and relations group and national community-based leadership) to select the Women's Caucus membership. Planning for the Women's Caucus face-to-face meeting began. The meeting will take place in conjunction with the HPTN / IMPAACT annual meeting in June 2010.
Objective #7: Coordinate HANC Legacy Project activities with other HANC cross network working group and projects				
Legacy Project Staff	Facilitate collaboration and harmonization among the various HANC working groups and projects.	Integration of the Legacy Project's focus on the populations most impacted by the HIV epidemic in the US into relevant HANC Working Groups for increased collaboration, harmonization and efficiency.	Ongoing.	Legacy Project staff established membership and participation on the HANC Behavioral Science Working Group, Site Coordinator Working Group, Community Partners and the Communications Working Group.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #8: Provide protocol support, especially where Legacy Project target populations are a major and or priority population for study enrollment.				
Legacy Project Staff	Participate on protocol teams, where applicable, and/or in advisory, leadership or other roles.	Provide insight, advice and leadership from the Legacy Project perspective and representing the Legacy target populations.	Ongoing.	Legacy Project Manager, Kaijson Noilmar and Steve Wakefield continue to be members of the HVTN 505 and HPTN 061 protocol teams. Kaijson is also the Co-Chair of the HVTN 505 Community Affairs Working Group, a member of the HVTN 505 Behavioral Studies Working Group and the HVTN 505 Community Affairs Working Group. Kaijson continues to be a member of the HPTN 061 Black Caucus and, was inaugural Chair of the Caucus and provides advisory support to current Caucus Chair. Kaijson also provides advisory and leadership support to HPTN 065 community engagement and relations activities and is the Legacy Project representative on the HPTN 065 Community Advisory Group.