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Infrastructure and Administrative Support

The HANC Public Website

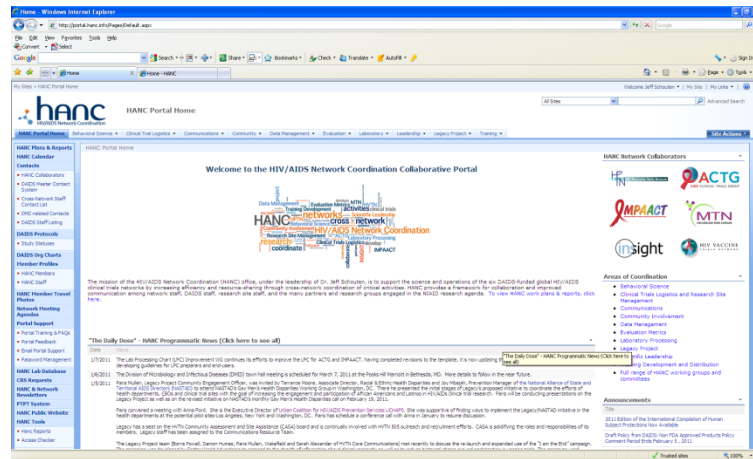
The HANC public website (www.hanc.info) provides information and resources for collaborators, research sites, and the general public. HANC released its newly branded site early in June 2010. Functionality and content added to the website this quarter included:

- Improved navigation
- Network responses to iPrEx study results and network newsletter library
- Links to community/trial participant resources
- Updated DAIDS organization charts
- OCSO SOPs
- Links to HANC’s Facebook and Twitter pages
- Easily updated program spotlight applet on the homepage: featured links to AIDS.gov “[Future Directions for NIAID HIV Research](#)” blogs
- Developed and launched the HANC blog: postings included “[What are your thoughts on the Community Partners Research Priorities?](#)” and “[Call To Action - Women and HIV Research Blog Comments Needed](#)”
- Added a “[Behavioral Science Publications](#)” link library
- Pages for the DAIDS-ES Applications Training Information



Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
HANC & IT staff	Public site updates and rebranding project.	Improved capacity, ease of navigation flow and access to information.	Ongoing.	Launched new site and HANC is in process of implementing phase II design plans. HANC staff has been uploading images and documents and created a Network Press Release Library , including network PrEP studies ongoing and in development, and the BSIG Publications Library .

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 33 individuals with HANC portal user accounts, for a total of 1,013 active HANC Portal user accounts. Two additional team sites were developed this quarter, including the Risk Assessment Focus Group and the Neurocognitive Focus Group, for a total of 63 team sites. HANC portal projects for 2011 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 has 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 all approved network protocols on the HANC portal to the DAIDS-ES document library.	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 and HANC IT staff is working with DAIDS-ES developers. Expected to be activated in Q4.
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 and navigation.
HANC staff	Upgrade to SharePoint 2010	Improved functionality and ease of use.	Ongoing.	Consulted with IT staff to determine feasibility and timeline and a test site has been developed.

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 bi-monthly to monthly. “HANC Portal 101s” are now offered on a monthly basis and “as requested” basis. HANC members are invited by HANC to participate in a walk-through of portal/website resources. HANC staff inaugurated monthly SharePoint trainings in Q2. The sessions focus on the collaborative features of SharePoint technology.

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 continues to propose topics for network meetings. The group is exploring the possibility of hosting symposia at the Spring 2011 HPTN and ACTG conferences.
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 BSIG 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 portal library has been created and is updated on an as needed basis. To date, over 410 documents have been loaded to the site. A Behavioral Social Science library with links to PubMed abstracts has been created on the HANC public website.
Objective #3: Collate and analyze behavioral data elements across network studies.				
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. Ongoing updates to the Network “Behavioral and Adherence Measures” table.	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. The “Behavioral, Adherence, and Neurocognitive Measures” table is updated on an as needed basis. The BSWG has reviewed network CRFs and BSS elements, and ACASI on calls/webinars.
Objective #4: 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.	The Working Group discussed ongoing network behavioral and social science activities and decided on focus group topics. The resulting Risk Assessment and Neurocognitive Focus Groups will meet in Seattle in April 2011 and produce white papers that will be submitted for publication.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #5: Study and promote the development and implementation cross-network/trans-Institute studies and/or behavioral data elements in network studies. Analyze funding and review procedures.				
Behavioral Science Working Group	Identify areas of opportunity and challenges in the development/implementation of cross-network/trans-Institute protocols.	Ensure that the best quality behavioral science is integrated into clinical trials; reduce redundancy.	Ongoing.	Discussed goals on monthly conference calls. Upcoming focus groups and full group F2F agendas will reflect this priority.
Objective #6: Improve information exchange among network-affiliated behavioral and social scientists.				
Behavioral Science Working Group, Behavioral Science Interest Group	Compile a list of network-affiliated behavioral and social scientists and create a "Behavioral Science Interest Group" (BSIG) distribution list modeled on the NLOG. The list allows investigators to share updates in the field, innovative research methods, and links to seminal papers.	Improved communication and circulation of ideas.	Ongoing.	Created BSIG listserv, portal-based resource center, and publications library on the public website. HANC circulates a weekly digest of newly published BSS articles, CRFs, funding opportunities, job openings, blog posts, etc. Over 250 behavioral and social scientists have joined the Behavioral Science Interest Group since its inception at the beginning of Year 5.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #1: Develop cross-network strategic message guidelines and recommendations for study results dissemination.				
Communications Working Group	Create a set of Best Practices for study results dissemination.	Harmonize network approach to communicating results and to reinforce the inter-connectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	HANC has been developing web pages to highlight network responses to iPrEx study results and created a network press release library. WG members are encouraged to share study results and HANC circulates announcements as able.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #2: Consider ways to harmonize network communications strategies and external relations policies.				
Communications Working Group	Areas of interest include: review and identify points of commonality across network websites; discuss network policies regarding posting protocol documents on public websites; network website recruitment strategies; links to outside parties including all other networks; evaluate 508 compliance on network websites.	Harmonize network communications activities and to reinforce the interconnectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	HANC paired networks and DMCs to review network sites with the goal of identifying possible areas of harmonization and considering how each network maximizes its web presence. Ongoing discussion of network policies around posting protocols or synopses. Discussed 508 compliance and circulated guidance documents. Discussed compiling a list of HIV/AIDS-related community-based organizations to add to the media list and post on the public website.
Objective #3: Develop a Communications Resource Center (CRC) on the HANC portal.				
HANC Staff	Create a portal-based library of communications resources including: articles, guides, presentations, contact information, Best Practices, and white papers.	Facilitate communication and share Best Practices across the networks and provide opportunity for clinical trials communications professionals to develop relationships.	CRC created. Updates ongoing.	The CRC is a library of communications resources including: articles, guides, presentations, contact information, best practices, and white papers. Network communications staff and professionals in the field have access to the site and are encouraged to contribute content. HANC staff demonstrated the CRC at the AVAC Communications WG meetings. Non-network partners include representatives from MMCI, AVAC, and IAVI. HANC is exploring expanding the CRC membership to a broad array of HIV/AIDS advocates and research organizations. HANC created an expansive media contact list for CRC members.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #4: Share IT- and communications-related developments across all areas of coordination.				
HANC Staff	Standing opportunity to share programmatic updates on conference calls across all areas of coordination. Examples include: the IT Best Practices document developed by the DMC Harmonization Working Group; Community Partners and the Site Coordinators Working Group concerns about IT needs at resource-limited sites; implementation and use of DAIDS-ES web services; privacy and IT security issues; Legacy Project activities in the field and use of social media.	Improved communication across networks and HANC activities.	Ongoing.	Cross-cutting issues are addressed on HANC calls and outcomes are shared via email. Programmatic updates are posted on the Daily Dose, Twitter, Facebook, and in the HANC newsletter. Guests are invited to join working group calls on an ad hoc basis. Q3 calls addressed HANC and network website redesign projects, strategies to encourage use of collaborative websites, and the value of protocol-specific websites. WG members discussed the cross-network trend towards making more documents available on the public websites as well as tips/considerations for networks as they advance through the redesign process. The DMCWG continues to discuss use of intra-DMC project management software and HANC updates other relevant WGs as necessary.
Objective #5: Review existing methods of evaluating communications efforts and consider which practices could be employed within the networks.				
Communications Working Group, IT Infrastructure Working Group	Areas of interest include: review existing website usage tools; share experiences using social network sites (e.g., Facebook and Twitter) and document web traffic generated from new media sites; discuss focus group guidelines and outcomes; community education strategies.	Leverage individual network successes and share lessons learned. To quantify communications outcomes with a mind to improved efficiency and effectiveness.	Ongoing.	Monthly discussion of network websites, use of social media, and ways to improve communication with network members and the general population. Much attention has been paid to social media tools. Pursued development and launch of the AIDS.gov Google map widget: the real-time map of DAIDS clinical trial sites will be displayed on hanc.info, on participating network websites, and on the AIDS.gov service locator. The group began discussing strategies to encourage use of collaborative websites and the value of protocol-specific websites. Q3 calls were dedicated to the development of evaluation metrics and community engagement practices.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #6: Review and make recommendations about communications best practices and evaluate available resources such as the Microbicide Media and Communications Initiative “Clinical Trial Handbook”.				
Communications Working Group	Review and recommend network communications Best Practices.	Harmonize network communications activities and to reinforce the interconnectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	Q3 was dedicated to distilling best practices and lessons learned from RV144, CAPRISA 004, and iPrEx communications campaigns. HANC is in conversation with AVAC to develop a protocol milestone calendar.
Objective #7: Invite key stakeholders, opinion-makers, and experts in the field to present on Working Group calls. Areas of expertise could include: journalism, advocacy, blogging, and cultural anthropology.				
Communications Working Group, IT Infrastructure Working Group	Engage communications professionals on monthly conference calls and ad hoc webinars.	Deepen understanding of new tools; learn from other organizations experiences and expertise; share ideas across an array of domains; provide opportunity for clinical trials communications professionals to develop relationships.	Ongoing.	iPrEX Communications Consultant, Mark Aurigemma, attended a call and discussed lessons learned from that study’s results dissemination plan. HANC staff participate on AVAC PrEP and Vaccine Communications Working Group calls and report back to the HANC-facilitated Communications Working Group.
Objective #8: Identify, implement, and maintain tools to improve cross-network communication.				
HANC staff	Maintain resources such as the DAIDS staff listing, data management related contact list, cross-network collaborator list, network newsletter library, archive of network meeting agendas, disseminate DAIDS and network updates.	Foster communication and access to contacts within the DAIDS and network structures.	Ongoing.	Updated libraries and resources as able; solicited articles from the networks for inclusion in monthly newsletters; posted updates and notices to the HANC portal’s Daily Dose, Twitter feed, and Facebook page. Standing opportunity to share programmatic updates on conference calls across all areas of coordination. Discussed partnering with AVAC to create a protocol timetable for HIV/AIDS clinical trials. Launched the HANC blog and invited networks to submit posts.

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.	Completed prioritization, disseminated results and are currently evaluating research gaps. Ongoing.	The group invited community advocates to review and provide feedback on the HIV research priorities through the HANC blog. Upon request from DAIDS the group was charged with identifying which research areas listed on the CP Research Priorities are not currently being addressed in ongoing or protocols in development. The group requested that the networks provide information on current protocols or protocols that are in development that address the CP Research Priorities to highlight the gaps and overlaps. This information will be presented to DAIDS at the March 2011 CP F2F Meeting.

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	Utilize the Community Training Working Group to share existing CAB training materials; identify and develop new or standardized cross-network CAB training materials as needed. Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups. Partner with groups to incorporate a human rights perspective into capacity building and research participation. In partnership with DAIDS, develop an eLearning module based on the current Community Training Materials, "Understanding the clinical research process and principles of clinical research" and "The role of a CAB and principles of community involvement"	Common CAB member understanding of basic concepts in HIV disease, clinical trials methodology, and CAB role. Improved training quality and consistency. The eLearning module will provide an introduction to clinical research using the current materials which will be appropriate for CAB members and new clinical research staff. In addition, there may be periodic offerings of a train the trainer webinar since some CAB members may not be able to take the online training and some sites may want to offer the training at their site.	Ongoing.	In partnership with DAIDS, the group began discussions on how to develop a more detailed CAB component specific to the development, membership, management, and involvement of a CAB at a site. The group reviewed a list of suggested training topics for community training not currently covered in the CAB Training module to determine the future focus of the group. The group focused on promoting attendance of CAB members at the upcoming DRTE CAB development training in Durban, South Africa in May 2011.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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. Developed and administered Site CAB and Site Staff Surveys to assess community participation at the site level. 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. Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites	Ongoing.	In collaboration with the EMTF and CP site-level funding WG formed a writing group and held conference calls focusing on drafting and publishing the results of the CP survey. The group began discussions on revising the CP Survey for 2011.
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. Developed and administered Site CAB and Site Staff Surveys to assess community participation at the site level. Partner with the network leadership to assess how the site funding mechanism has impacted community involvement at the network, CTU and CRS level. <ul style="list-style-type: none"> 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. Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites	Ongoing.	In collaboration with the EMTF and CP site-level funding WG formed a writing group and held conference calls focusing on drafting and publishing the results of the CP survey. The group began discussions on revising the CP Survey for 2011.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Provided feedback and input to DAIDS on the upcoming recompetition and restructuring process. Developed an agenda for the March 2011 CP F2F Meeting.
Objective #6: Review the following topics across the networks; identify areas where there are problems or opportunities for improvement and work in collaboration with Network Leadership and DAIDS to address these issues.				
Community Partners Ethics Working Group	Solicit input from networks and other groups to provide input and recommendations to DAIDS and Network Leadership regarding: Informed Consent Process Management of Pregnancy and Contraception on Study Trial design relative to guidelines/local standard of care Placebo arms in prevention trials	Identify areas where there are problems or opportunities for improvement to address these issues.	Ongoing	Held conference calls and began focusing on management of pregnancy and contraception while on study, which will include collaboration with the HANC Women's Research Collaborative. Continuing work with OPCRO to review and address the scientific, clinical, ethical, community and personal issues at stake in dealing with contraception and pregnancy in the context of clinical research participation.

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 3 at DAIDS clinical trials study sites/affiliated laboratories and monitor infrastructure changes.				
DMC Harmonization Working Group	Implement Information Technology Best Practice Standards developed in Year 3 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. Created IT Best Practices Document Task Force to review the documents, make recommendations, and consider possible application of IT Best Practices at DAIDS-funded sites. The Taskforce includes representatives from the DMCs, OCICB, and DAIDS. The group developed and launched a survey assessing the sites' IT challenges and practices.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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.	Facilitated conversation amongst cross-LIMS partners. Determined feasibility and timeline for implementation. Resolution expected by the end 2011.
Objective #3: 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 #4: Harmonize MedDRA coding.				
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 weekly reviews with DAIDS-affiliated clinicians.
Objective #5: Harmonize data definitions and standards for compatible all-network use.				
DMC Harmonization Working Group	Identify data elements to be harmonized across network studies.	Improve efficiency and harmonization. Allow for cross-network studies/analyses.	Ongoing	DMCs are considering higher priority areas for harmonization and provided suggestions to DAIDS. Project formally on hold pending DAIDS' recommendations. DMC members have participated in discussions to harmonize behavioral elements in network studies.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #6: Implement clinicaltrials.gov results reporting requirements.				
DMC Harmonization Working Group	Network Leaders asked that HANC work with DMCs to address cross-network issues and points of ambiguity.	Improved communication.	Ongoing.	Opportunity to share updates on monthly calls. HANC reports on Site Coordinators WG and Network Leader comments as appropriate.
Objective #7: 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 and adverse event reporting.	Ongoing.	This objective is addressed in ongoing calls with OPCRO and the DMC Harmonization Working Group. The WG discussed the changes to the DAIDS EAE Manual on monthly calls. HANC worked with DAIDS and RSC to create a "Protocol Reporting List" to help networks and sites identify protocol-specific EAE Manual reporting requirements. HANC disseminated DAIDS-issued memos.
Objective #8: 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 invited DAERS product champion to join a call and discuss the process for QC and RSC's role in reviewing the data and generating reports.
Objective #9: Coordinate a one day DMC face-to-face meeting.				
DMC Harmonization Working Group	DMC representatives will use the time to present ongoing intra-DMC projects and consider additional areas of coordination.	Improve efficiency and harmonization.	On hold.	On hold pending further discussion and identification of agenda items.
Objective #10: Create an email alias for DMCs and network operation center staff. The list serve will be a vehicle to share important DAIDS updates and HANC working group activities.				
HANC Staff	Create a DMC/network operations center staff alias.	Improved communication across DMC and network operation staff.	Q1.	Completed. The alias is used for relevant DAIDS' memos and policies and cross-cutting updates.

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 calls as needed 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.	<p>Calls with the EMTF planning group are ongoing monthly.</p> <p>A writing group is drafting a manuscript on the feedback collected from the Site CABs and Site Research Community Coordinators survey. The protocol implementation timeline analysis is ongoing. A manuscript on the bibliometric analysis was published in PLoS ONE on March 4, 2011.</p> <p>The pluripotent study WG was formed and will hold their first call in March.</p>

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	Maintain a Lab Tech (LT) Committee Workload Tracking System; generate reports as requested.	Track information about LT work assignments to ensure equitable sharing of responsibilities and accurate awarding of credit.	Maintain and update data throughout the year; Q3 further develop reporting system	Updated the LT Workload Tracking System with current protocol and lab tech information in an ongoing manner.
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 1 set of laboratory working group updates.
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	<ul style="list-style-type: none"> Held 4 calls during which the group: <ul style="list-style-type: none"> Reviewed progress of the Abbott m2000 implementation Reviewed the marking of critical items on action plans Discussed options for tracking and sharing training records of sessions conducted at network meetings Determined priorities for laboratory training Determined LFG goals for 2011 Considered a proposed process for local validation of FBS lots Reviewed process for cross-network communication

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
				in the event of a PT failure Submitted a request for translations of the online GCLP refresher course
HANC Support Staff	Maintained and updated 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 Regularly updated VQAAB reports and minutes Updated Useful Links page in Laboratory Resources Expanded information for ACTG and IMPAACT labs
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.	On hold during Q3 pending upgrade of the HANC portal to SharePoint 2010.
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.				
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.	<ul style="list-style-type: none"> Held 2 calls during which the group: Discussed and resolved testing issues at labs Reviewed and revised a draft validation plan Considered and agreed to serve as an advisory group for the domestic CD4 PT program Reviewed lab-network affiliations and PT program participation for the upcoming year
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 11).	This project was on hold during Q3.
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.	Reviewed proficiency testing (PT) summaries and resolved specific laboratory issues. Determined group goals for 2011. Reviewed ACTG laboratory cryopreservation certification requirements.
ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository.	Reliable results in functional and phenotypic assays.	Q2 Review results of pilot study; Q4 Collect and analyze additional samples, evaluate results	This project was on hold during Q3.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
ICAG	Consider the feasibility of using functionality data from researchers to determine the quality of similar samples stored at BRI.	Reliable results in functional assays.	Q3 Initiate a pilot study; Q4 Submit example data to statisticians for review and recommendations	Initiated pilot study
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.	Q2 Review and revise; Q4 Finalize and post	In progress.
CPQA Advisory Board	Maintain a structure, processes and a forum for consistent communication about the CPQA PT program.	Consistent quality control of pharmacology testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 2 calls during which the group received updates from the CPQA and the other networks.
CPQA Cross-Network Lab Group - Technical	Maintain a structure, processes and a forum for consistent communication among the CPQA laboratory technicians.	Consistent quality control of pharmacology testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 1 call during the which the group: Received updates from the CPQA Discussed options for testing assay selectivity Discussed the development of an assay complexity scoring system
CPQA Cross-Network Lab Group - Scientific	Maintain a structure, processes and a forum for consistent communication across the CPQA laboratory PIs.	Consistent quality control of pharmacology testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 1 call during which the group discussed how the NIAID recompetition will affect the CPQA program.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Virology Quality Assurance Advisory Board (VQAAB)	Maintain a structure, processes and a forum for consistent communication about and performance review of VQA labs. Review data and revise policies of the VQA PT program as necessary	Consistent quality control of virology testing at network-affiliated laboratories.	Ongoing throughout the year.	Held 3 monthly calls during which VQAAB: Reviewed PT reports and cumulative performance summaries Received updates from the VQA on a new PT panel for drug resistance mutations in the integrase gene, a dried blood spot study that was conducted with the HIV DNA PT panels. Discussed the potential to offer HPV, HBV and HCV testing Discussed a potential change to how accuracy scoring is determined Reviewed a proposed panel for validating a switch from the Roche TaqMan version 1 to version 2.
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 Processing Chart (LPC) standard wording and format.	Improve design of LPC for efficiency and user-friendliness and update standard wording to reflect current practice.	Q2 Complete updates to standard wording and conduct reviews and initiate reformatting; Q3 Develop user guides; Q4 Finalize standard wording in light of approved template	Completed reformatting of LPC templates and drafting of user guides.
PBMC SOP WG	Develop, finalize, translate and post version 3 of the Cross-Network PBMC Processing SOP.	Standardize PBMC cryopreservation across the networks to ensure access to high-quality specimens for use in network studies.	Q2-4 Revise; Y6Q1 Post; Y6Q2 Initiate translations	<ul style="list-style-type: none"> Held 5 calls to review suggested changes and further harmonize the SOP.
Lab PI/Mgr Committee/HANC Staff	Develop a Laboratory Certificate Library on the HANC public website.	Provide one location for the upload/download of lab certificates to reduce duplication of effort for labs and sites that need access to the certificates.	Q3-4 Develop Lab Certificate Library; Q4 Populate and launch library	<ul style="list-style-type: none"> Developed laboratory certificate library.

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 2 calls to: Review a sputum collection/transport kit being developed by Northwestern University and the University of Cape Town Discuss options for addressing ACTG Site Personnel Safety Issues Review EQA updates Discuss laboratory structure, pediatric participation and EQA for A 5295
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.	Placed on hold in Year 4.	This project is on hold.
Objective #5: Collaborate among the networks, HANC, DAIDS and SMILE to establish a Malaria Laboratory Working Group.				
Malaria Laboratory Working Group	Determine working group membership, purpose and goals	Establish a forum for cross-network communication regarding malaria laboratories and diagnostics.	Q2 Establish membership and initiate discussions of working group purpose and goals; Q2-3 Share critical information across group members in order to finalize working group purpose and goals	Held 3 calls to: Share updates with the ACTG and IMPAACT malaria groups and discuss opportunities for collaboration Review and discuss an overview of PCR assays for malaria diagnostics Review and discuss the development of standard SOPs for malaria serological testing

Legacy Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #1: Continue the development of the 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.	With the leadership of Damon L. Humes, MHS, the Legacy Project team manages a broad range of activities aimed at expanding the project’s visibility, reach and impact. Additionally, a Strategic Planning Task Force (SPTF) was established to give input into strategies that would refine the project’s scope, intent, timeline and criteria to determine project success. The SPTF, Legacy Project staff, and consultant Louis Graham, PhD have drafted a strategic plan for Legacy Project Working Group (LPWG) review. LPWG feedback will be captured during the LPWG Meeting, March 24-25, 2011. Efforts to recruit a Social Scientist are ongoing.
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.	Ongoing.	Regular meetings were held with the HVTN Community Relations and Education Unit, Legacy Project, Site Expansion Team, and Community Assessment & Site Assistance Group (CASA). Legacy Project staff participated to support cross-network expansion. Steps taken to expand the Legacy Project beyond the HVTN included substituting the term “HIV clinical research” in place of singular references to individual network research to allow for a cross-network approach and increased opportunity to support a wide range of prevention and therapeutic research studies.
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.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Legacy Project Leadership Team	Develop definitions and expectations.	Clear distinction but also coordination of programmatic activities to assure efficient implementation of both HVTN and expanded network activities.	Ongoing.	<p>The Legacy Project utilized interdepartmentally-coordinated meetings and trainings to share information and resources that would support successfully accomplishing HANC and HVTN activities. These meetings were used to uncover duplicative efforts, increase community involvement and collaboration, and expand collaborative relationships within all DAIDS-funded networks, and health and human service agencies across the US. Meetings were held with the HVTN Community Relations and Education Unit, Site Expansion Team and Community Assessment & Site Assistance Group (CASA). Legacy Project staff participated to ensure increased opportunities for cross- network expansion. Additionally, monthly meetings were held between the Legacy Project, HANC and HVTN directors to ensure programmatic distinction; while seeking opportunities to collaborate and coordinate efforts. These meetings provided directors an opportunity to review cost/benefits from attending conferences and special interest meetings; as well as discussed strategies to build on existing successes and make corrective action to overcome barriers. Budgets were also reviewed and financial resources were allocated to support activities.</p> <p>The Legacy Project's Workgroup members, which represent HANC, the Networks and Community Partners constituencies, have helped to identify strategies that ensure synergy and cohesion.</p>
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 relationships between the Legacy Project and each of the networks.	Ongoing.	<p>Held monthly LPWG calls which focused on mission, structure, function and group membership and planning for the April LPWG face-face meeting. Expanded network representation in the LPWG includes: ACTG, HPTN, MTN, and INSIGHT. Representation from the HVTN remained the same.</p>

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.	The LPWG held monthly calls which focused on issues pertaining to the structure of the group and subgroups. The LPWG and LPWG Strategic Planning Task Force continued to meet throughout this report period. Louis Graham, DrPH, was contracted in December 2010 to assist with the strategic plan; specifically to field varying interests from LPSWG members, external collaborators and community members. He also conducted an exhaustive literature review and co-authored the strategic plan (currently in draft). He worked collaboratively with the Strategic Planning Task Force, Damon Humes, Jeff Schouten and Legacy Project staff.
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, and women with experience working with these populations.				
HANC Women’s HIV Research Collaborative formerly reported as 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.	Ongoing.	Borris Powell coordinates the Legacy Project Women’s HIV Research Collaborative (WHRC) under the leadership of co-chairs Kate Miller (HVTN Global CAB) and Georgette King (HPTN). The WHRC has diverse representation from all six DAIDS networks and meetings occur monthly. The group formed the following subcommittees: 1) Community relations and outreach, 2) Microbicide, and 3) HIV Positive Women (issues related to living positive). The <u>Women’s Call to Action Document</u> was written and disseminated nationally through DAIDS blogs and through social media sites such as Facebook. The document was placed on the HANC portal and public sites for continued access. Comments were invited in regards to the upcoming network restructuring. A face to face meeting of the WHRC will occur on May 23-24, 2011 in Miami FL.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 Coordinators Working Group, Community Partners, and the Communications Working Group. Paris Mullen represents Legacy on the HANC Communication Working Group and the Site Coordinator Working Group. Legacy Women and HANC Community Partners are in communication about addressing ethical issues focused on women and pregnancy in research. WHRC presented an overview of their goals and directions to CP. Negotiations are underway to convene a joint meeting of WHRC and CP on issues related to pregnancy and women in HIV research.
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 represent the Legacy target populations.	Ongoing.	Legacy Project program staff provided protocol support through consistent and active participation on the HPTN Black Caucus. Legacy staff served as advisors; while providing focused leadership in support of HPTN 061 recruitment and engagement activities, and participated in the HPTN 061 Retention Retreat. During the retreat, Legacy Project staff emphasized the importance of engaging minority communities and provided technical and capacity building assistance (e.g. recruitment strategies and lessons learned) to attendees. The HPTN's Black Caucus has a cultural responsiveness trainings and document under development, Borris Powell has been an integral part of creating relevant frameworks for these processes. Legacy Project had representation on the HPTN 065 Community Advisory Group. Participation on this advisory board has led to the development and completion of frequently asked questions (FAQ) document for use by HPTN 065. Legacy membership to this advisory board is ongoing.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #9: Collaboration between the HANC Legacy Project and historically African-American organizations				
Legacy Project Staff	Strategies and activities to support this objective: The Legacy Project will work with leadership from these organizations.	The purpose would be to develop a national campaign or strategy unique to each specific organization that would raise awareness and educate the African-American community about HIV prevention and treatment research, and engage in discussions about ongoing and planned HIV clinical trials.	On hold pending completion of the Legacy Project strategic plan in Q4.	<p>The Legacy Project engaged in dialogue and collaborative activities with historical Black colleges and universities (HBCU) and leaders within the house/ball community. The HBCU Initiative was designed to increase awareness of prevention and therapeutic research opportunities for African Americans who were or who are currently enrolled in HBCUs. The project will also mobilize key leadership within HBCUs (personnel and students) to determine the most effective strategies to increase trust of medical providers and government; thus reducing HIV stigma. Initial meetings were held in Mid-January 2011 between the Legacy Project and leadership from South Carolina HIV/AIDS Council; whom currently operates a HBCU HIV prevention initiative on several campuses in the south (Atlanta, North & South Carolina).</p> <p>Legends Care Project: The Legends Care Project hosted an initial meeting with the Philadelphia Ballroom Alliance to provide intensive education about HIV biomedical research. Local leaders gave guidance on ways to engage house leadership about HIV biomedical research. The local alliance decided that a partnership with the COLOURS Organization and the University of Pennsylvania's Vaccine Trial Unit would help to reduce mistrust.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #10: Collaboration with the Black AIDS Institute (BAI) sponsored Black Gay Men's Network (BGMN)				
Legacy Project Staff	Provide leadership, workshops, access to and information regarding the importance of biomedical research and HIV/AIDS clinical trials in African American MSM communities. Facilitate cross network collaboration and information at BGMN events. Educate the network about the technology and science of HIV/AIDS treatment and prevention.	Establish a relationship with the Black Gay Men's Network that will allow for an increase in the participation and engagement of African American men into DAIDS-funded clinical trials, as well as to educate this demographic of almost 800 African American men about the science and research involved in HIV/AIDS treatment and prevention. Provide DAIDS-funded cross-network exposure to the membership of the BGMN.	Ongoing	Paris Mullen, Community Engagement Officer, served as Leadership Development Co- Chair for the BGMN. In this role, he facilitated the distribution of cross network materials and coordinated recruitment and educational opportunities for clinical trial sites at BGMN events. The Black Gay Men's Network is planning their annual retreat in the Dominican Republic March 31-April 4, 2011. The Legacy Project will address numerous topics as they pertain to Black gay men and their identities; as well as discuss recent advancements within HIV biomedical research (e.g., iPrEX, RV144 and CAPRISA 004) and their impact on African American MSM communities.
Objective #11: Legacy Expanded Testing Initiative				
Legacy Project Staff	The <i>Legacy Expanded Testing Initiative</i> is a collaboration under development between DAIDS-funded clinical trial sites, health departments and community-based organizations in the following jurisdictions: New York City, Los Angeles, Washington DC and Philadelphia. LETI objectives are to 1) increase awareness of HIV biomedical research, 2) provide education on the relevance of HIV biomedical research within communities of color, 3) promote participation in HIV/AIDS clinical trials and 4) encourage referrals to trial sites during pre/post test HIV counseling and testing.	LETI ultimately seeks to increase the engagement and participation of disproportionately impacted communities in HIV prevention and treatment clinical trials.	LETI anticipates being fully operational by August 2011.	In November during the HVTN Full Group meeting Paris Mullen met with Joy Mbajah, Prevention Manager for NASTAD. He presented the initial LETI proposal. He asked her how Legacy could help increase the engagement of disproportionately impacted by HIV into HIV clinical trials. After their discussion Joy and Terrance Moore, Associate Director, Racial & Ethnic Health Disparities invited Paris to present the LETI proposal to NASTAD's Gay Men's Health Disparities Working Group in Washington, DC. This group consisted of HIV Prevention Directors at health departments from across the country. The Urban Coalition of HIV/AIDS Prevention Services (UCHAPS) and the HIV Prevention Trials Network (HPTN) have agreed to partner with Legacy in the creation and implementation of LETI.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #12: Engage and collaborate with organizations representing Legacy target populations to increase awareness and support of HIV clinical research.				
Legacy Project Staff	Provide education about the HIV clinical trial process; develop relationships based on trust and increase awareness of the work of the 6 NIAID-funded HIV/AIDS clinical trials networks and their studies. Also foster linkages with local Clinical Trial Units and Research Sites and community organizations representing Legacy target populations regionally.	Engage and educate communities about DAIDS- funded networks to increase participate of under-represented populations in HIV/AIDS clinical prevention and therapeutic trials.	Ongoing	<p>Two focus groups were conducted by the Legacy project at the 2011 National African American MSM Leadership Conference on HIV/AIDS and other Health Disparities (NAESM) in January 2011. Legacy hosted a plenary session, co-sponsored by the HPTN, on HIV biomedical research in the NIAID Clinical Trials Networks with the participation of Ian McGowan, Co-PI of the Microbicide Trials Network and Magda Sobieszczyk and Scott Hammer of the HVTN 505 protocol team. The plenary was followed by a workshop which gave community members an opportunity to discuss specific aspects of the research with the scientists. The Legacy Project also had an exhibitor booth which was used to host recruitment staff from New York Blood Center and Project Achieve. Local site staff utilized the opportunity to recruit potential participants attending the conference.</p> <p>Legacy Project staff attended the 2011 Creating Change Conference; where Parris Mullen conducted a Health Institute and Borris Powell facilitated a workshop. Both served as members of the planning committee, Paris was responsible for conducting bi-monthly CC2011 Health Institute planning committee calls. The conference took place February 2-6, 2011 in Minneapolis, MN. The workshop topics were: the National HIV/AIDS Strategy for the United States; the United States Health Care Reform law; Healthy People 20/20; and Advocacy 101.</p>

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held one call this quarter, in January, during which Jonathan Fuchs and Jeffrey Schouten presented an overview of the recently deployed HIV Research Counseling and Testing Project (HRCT) available on the DAIDS Learning Management System. The Strategic Working Group did not meet this quarter.

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 two conference calls in this quarter to collaboratively identify and address issues and share updates on activities.

HANC had one call with OCSO leadership and was in frequent contact with OCSO to discuss the Protocol Costing Project and distribute policies in development to the Network Leadership Group and the core/operations centers. HANC also held one call with OPCRO leadership during which OPCRO presented updates on the DAIDS EAE Reporting Manual Version 2.0; ClinicalTrials.gov reporting; and the MedDRA Implementation Working Group was discussed. HANC continued to work with OPCRO on the implementation of the “Manual for Expedited Reporting of Adverse Events (EAEs) to DAIDS”, version 2.0. HANC also updated OPCRO on the proceedings of the financial disclosure working group and the protocol costing project. Sandy Butler of the RSC participated in the January 2011 DMC Harmonization Working Group call. HANC Director Jeffrey Schouten attended the February 7, 2011 NIAID Council and ARAC meetings.

Site Management & Logistics Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #1: Work closely with network staff and DAIDS representatives to review the harmonized network Financial Disclosure/Conflict of Interest requirements, synchronize network financial disclosure reporting schedules, and evaluate the feasibility of developing a cross-network web-based reporting interface.				
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. Realize the cost-saving opportunity possible with a cross-network reporting system.	Completed SOP in Y4. Scope discussions are ongoing and will be completed by Q3.	The SOP was approved by Network Leaders in Q4 of Y4. The WG is now harmonizing the definition of members required to report and discussing the implementation of a cross-network online reporting system.
Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS representatives 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 one call with OCSO. HANC had frequent communication with OCSO to continue discussions around the Protocol Costing Project.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #3: 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.	Jeff Schouten presented an overview of the HRCT training curriculum to the WG. The WG provided feedback on the Protocol Costing Project and the IT Best Practices Task Force site survey. Issues that have emerged from the monthly calls have been communicated and resolved with OCSO.

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.	Ongoing updates on the DAIDS Learning Management System (DLMS) which include new features and new trainings available were provided to the Committee. Updates to the upgrade on the DLMS were also provided. A demo of the HRCT curriculum was shared with the committee and how to best plan webinars to share with their site staff. Training requests were submitted via the Training Request Mechanism on the HANC portal for the ACTG and IMPAACT Spring network meetings. The DAIDS ON TRAC WG provided feedback on their progress of centralizing training communications and information and asked for volunteers from the HANC Training Committee and Site Coordinators WG to participate. . DAIDS announced a DAIDS Regional Training Event to take place, May 2011, in Durban, South Africa.
Objective #2: Finalize, revise and deploy the HIV Research Counseling and Testing eLearning curriculum addressing risk reduction and adherence counseling in biomedical prevention and treatment trials.				
Risk Reduction Counseling Training Development 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 English version of the curriculum was launched via the DLMS on December 1, 2010 and the Spanish version was launched on January 31, 2011. HANC deployed the curriculum in the following ways to date. On the following HANC Calls: NLOG, Training Committee, Site Coordinators, Network Leadership. Webinars: HANC conducted 2 cross-network HRCT overview sessions for site staff and joined the ACTG site coordinator call. HANC newsletter and mass email distribution to all HANC collaborators.

Protocol Costing Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #1: Recommend to DAIDS method(s) for costing clinical trial protocols that could be applied to all Clinical Trial Units/Clinical Research Sites for all trials sponsored by DAIDS through any of its Clinical Trial Networks.				
HANC, working with an ad hoc working group on protocol costing	Identify and recommend a uniform method(s) for estimating the costs for the participation of DAIDS CTU/CRSs in trials sponsored by any of the DAIDS clinical trial networks. Recommendations must take into account relevant issues impacting the CTU/CRSs and the Network Operation Centers, and build upon what is currently working well in the Networks.	To define methods for incorporation into the next round of Cooperative Agreements.	June 1, 2010-February 28, 2011.	The final set of recommendations was drafted and discussed on a conference call in January with the Protocol Costing WG. The networks agreed to the final set of recommendations and a final report was submitted to DAIDS at the end of January. A Protocol Costing template was drafted for possible use by the networks and will be shared in Q4.