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Infrastructure and Administrative Support

The HANC Public Website

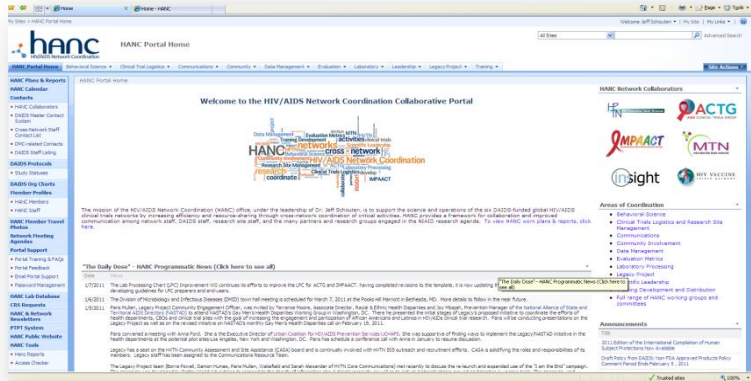
The HANC public website (www.hanc.info) contains a calendar of events, network newsletters, general information about HANC's coordination activities, training resources, laboratory resources, and other resources for collaborators, research sites, and the general public, including:

- A dynamic calendar of scientific conferences, network meetings, community events, training opportunities and more.
- Some of the Division of AIDS' Office of Clinical Site Oversight Clinical Research Policies and Standard Operating Procedures that are not listed on the DAIDS website and a link to the official versions of all current DAIDS Clinical Research Policies that are posted on the NIAID/DAIDS website.
- A dynamic announcement section on the home page for posting important notices, such as the iPrEx , CAPRISA 004, HPTN 052 and Partners PrEP study results and DAIDS policies.
- An HIV News section with the most recent HIV news and research findings via RSS feeds.
- Information for community members interested in supporting HIV/AIDS research as a community advisory board member.
- Links to clinicaltrials.gov for individuals interested in participating in a clinical research study.
- Free online Good Clinical Practice, Human Subjects Protection and Responsible Conduct of Research Training through the Collaborative IRB Training Initiative (CITI), and DAIDS-ES Applications Training Information.
- A map showing locations of networks and research sites around the world.
- Information for laboratories, including Standard Operating Procedures, a Laboratory Certificate Library, and VQA Resources.
- Library of all the network publications cataloged in one central location for ready access on the HANC public website including network press releases and responses to study results such as iPrEx.
- The HANC blog as well as an easily updated program spotlight applet on the homepage: featured links to AIDS.gov "Future Directions for NIAID HIV Research" blogs.



Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC & IT staff	Public site updates and rebranding project.	Improved capacity, ease of navigation flow and access to information.	Ongoing.	HANC is in process of implementing phase II design plans of last year's redesigned public web site. HANC staff has been uploading images and documents and created a Network Press Release Library and BSIG Publications Library .

The HANC Portal



The HANC Portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. The HANC portal includes document libraries; document development and version control management tools; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; and a cross-network directory linked to the DAIDS-ES Master Contact system. During Q1 we added 33 new portal users, for a total of 1,013 active HANC portal user accounts and 63 secure team sites (2 new ones created in Q1 and 3 sites retired) are used by specific cross-network working groups for collective document development, online discussion, and sharing of materials and information. HANC regularly solicits suggestions for the portal and updates the site accordingly.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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 are 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. Due to connectivity challenges to the DAIDS-ES database after a system upgrade we lost connectivity to the data feed in Q1. We hope to re-establish it in early Q2.
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.	Q2	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 Q2 with re-establishment of the DAIDS-ES data connectivity.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Adding features and resources for HANC members.	Improved resource and information sharing amongst HANC members.	Ongoing.	Expanded the member profile library, and continued refinement to the portal homepage and navigation.
HANC staff	Upgrade to SharePoint 2010	Improved functionality and ease of use.	Completed in Q1.	Completed migration of the HANC portal to a SharePoint 2010 base as well as migration to new servers at FHCRC Center IT with increased Center IT maintenance support negotiated.

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 monthly. “HANC Portal 101s” are now offered on a 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. HANC will provide individualized trainings for networks and affiliated partners as requested.

Behavioral Science Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science, take stock of lessons from related domains, provide new and ongoing adherence counselor training, elicit community working group input on adherence measurement and counseling, etc.				
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 and facilitate planning as requested and able.
Objective #2: Create a repository of measures, data forms, and standardized core elements of interventions accessible to partnering networks. The documents and links will be housed on the HANC public website and/or the HANC portal.				
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 500 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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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, statistical modeling, validating qualitative measures, and ACASI on and calls/webinars.
Objective #4: Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings and workshops. The Working Group will host a face-to-face behavioral science meeting in Year 6.				
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 finalized reports from the 2010 BSWG F2F, Risk Assessment Focus Group, and Neurocognitive Assessments Focus Group reports. The resulting Risk Assessment and Neurocognitive Focus Groups are exploring the feasibility of producing white papers and may be considered for publication. The WG will coordinate follow-up to the HANC Risk Assessment Focus Group report with the NIAID and USAID groups addressing similar issues.
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 scientific 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.	HANC consulted with ATN, NICHD, and NIMH leadership on the opportunities for a cross-network behavioral science scientific agenda. Discussed goals on monthly conference calls. HANC will continue to follow-up on discussions within DAIDS or the related Institutes around the challenges associated with having regulatory reviews for “low-risk” behavioral studies.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #6: Improve information exchange among network-affiliated behavioral and social scientists. HANC will continue to manage a “Behavioral Science Interest Group” list serve and resource center whereby researchers can receive updates from the field, links to influential articles, network study updates, meeting information, etc. HANC will continue to host a “BSIG topics of interest” webinar series.				
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 350 behavioral and social scientists have joined the Behavioral Science Interest Group since its inception at the beginning of Y5Q1.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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 webpages to highlight network responses to iPrEx, HPTN 052, Partners PrEP and other major study results and created a network press release library. WG members are encouraged to share study results and HANC circulates announcements as able. Each network identified a “communications point person” and shared this information with NIAID’s communications office. Network community liaisons joined the group so as to better reflect the needs and concerns of community members and site staff.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Consider ways to harmonize network communications strategies and external relations policies.				
Communications Working Group, IT Infrastructure	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 inter-connectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	Added HIV/AIDS-related community-based organizations to add to the media list and post on the public website. The IT Infrastructure WG began discussions with NIH around the use of a “single sign-on” authentication model which would allow network members to use a single set of credentials across all applicable network/SDMC websites.
Objective #3: Maintain and expand the 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 and a media list featuring over 400 international contacts.	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, USAID, and IAVI. HANC has expanded the CRC membership to a broad array of HIV/AIDS advocates and research organizations. HANC created an expansive media contact list for CRC members. HANC staff and collaborators maintain the list.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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. Q1 calls addressed HANC and network social media 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. HANC staff meet monthly to discuss issues that cut across the community, behavioral science, communications, training, site coordination, and Legacy Project areas of coordination.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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. Q1 calls were dedicated to the development of evaluation metrics. The WG met with Concept Systems Inc. to discuss the communications evaluation initiative under development. The group decided to assess the network's current communications channels and the effectiveness of external relations activities. Possible areas of interest are materials made available to sites and the impact of dissemination of study results.
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". Develop new tools such as a "Social Media Best Practices for HIV/AIDS Clinical Trial Networks."				
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.	HANC is working with AVAC to develop a protocol milestone calendar and is collating social media guidelines to incorporate into a "Social Media Best Practices for HIV/AIDS Clinical Trials". The latter will focus on ethical issues and tutorials for developing/maintaining social media presence.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #7: Invite key stakeholders, opinion-makers, and experts in the field to present on Working Group calls. Areas of expertise could include: journalists, advocates, bloggers and communications professionals.				
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.	HANC staff participates on AVAC PrEP and Vaccine Communications Working Group calls and report back to the HANC-facilitated Communications Working Group. HANC presented on an AVAC Vaccine, PrEP, and Microbicides Communication WG calls. The Communications WG invited HIV/AIDS advocates from IRMA and TPAN onto a call to discuss the current and changing state of advocacy and how the networks can learn from the advocate communities. HANC kicked off the “Communications Topics of Interest Webinar Series” with a discussion of using Facebook for clinical trials. The series will be open to network operation center and site staff. The success of the first webinar led to an ACTG-specific presentation. Upcoming topics include: Twitter, Google+, graphic design for the web, and using social media for recruitment.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #8: Consider coordinating a one-day face-to-face meeting. Network and partner representative will use the time to discuss upcoming communications priorities, network restructuring and consider additional areas of coordination.				
Communications Working Group	Host a communications-focused meeting for network staff and affiliated partners.	Facilitate the sharing of information, increased collaboration; leverage the experiences and expertise found within the networks.	Q1 and ongoing.	Hosted a one-day “2011 DAIDS HIV/AIDS Clinical Trials Networks' Communications Symposium” in which the attendees discussed: the NIAID Communications Office and DAIDS’ SCIB responsibilities; lessons learned from CAPRISA 004, FEM-PrEP, HPTN 052; the NHVREI project evaluation outcomes; network priorities in light of recent trial results and the upcoming recompetition, the Communications Evaluation Initiative, the Legacy Project strategic plan, and next steps for the WG. In addition to developing the Social Media Best Practices and structuring the Communications Initiatives, actionable items include establishing a “Communications Topics of Interest” webinar series, collating leak strategies, working with communications staff to identify and circulate key messages, and harmonize study results dissemination through promotion on the HANC public website.
Objective #9: 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. Continued promotion of the HANC blog and invited networks to submit posts.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop a community research priorities agenda.				
Community Partners Research Priorities Working Group	Draft a clear written outline of the project scope, intent, timeline and criteria to determine project success. Identify CP members 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. Outline specific community concerns/priorities for research in the various areas identified as research priorities.	Completed evaluating research gaps and are currently developing specific research items/concerns Ongoing.	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 was presented to DAIDS at the March 2011 CP F2F Meeting. Based on the presentation at the March 2011 F2F Meeting, the group expounded on the list of research priorities and are developing more specific research items/concerns under each community concern/priority research area.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Utilize the Community Training Working Group to share existing CAB training materials; identify and integrate materials 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	<ul style="list-style-type: none"> 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. 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. Create simple training materials from existing content describing Community Partners as well as the science and structure of the networks. 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 that 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 access the online training and some sites may want to offer the training at their site.	Ongoing.	In partnership with DAIDS, the group is developing two eLearning modules based on the CP Training Materials that will be available on the DLMS. The group developed a flyer to promote the CP Training Materials at various events and meetings. The group is working to contact non-DAIDS ASOs and CBOs to promote the CP Training Materials. The group is working on developing a cross-network training for staff who work with CABs.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: CP will 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	<ul style="list-style-type: none"> 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. 	<p>Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.</p> <p>Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites</p>	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 revised and distributed the CP Survey for 2011 that is due October 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	<ul style="list-style-type: none"> 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. Identify expectations for CAB support and funding that tie into cross-network community evaluation and make actionable recommendations to network leaders and DAIDS. 	<p>Adequate site-level CAB support.</p> <p>Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites</p>	Ongoing.	In collaboration with the EMTF and the 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 manuscript developed was submitted for publication. The group revised and distributed the CP Survey for 2011 that is due October 2011.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming network restructuring.				
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. Working on developing partnerships with TB and Hepatitis C advocacy groups as part of the NIAID restructuring process.
Objective #6: Gather and collate information on community engagement mechanisms that are best practices across sites and share across networks and with DAIDS.				
Community Partners Ethics Working Group	Solicit input from networks and other groups to provide input and recommendations to DAIDS and Network Leadership regarding: <ul style="list-style-type: none"> • 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 collecting information from the various networks regarding how the networks assess understanding of informed consent. Held a conference call and invited Dave Metzger on the call to discuss the issue of using incentives to help with retention of informed consent. Working with DAIDS to assist in updating the DAIDS document regarding assessing understanding of informed consent. Presented during a Cross-network Training Working group call the idea of developing a cross-network module dealing with assessing understanding of informed consent. Began working with DAIDS to develop an eLearning module addressing the issue of assessing understanding of informed consent.

Objective #7: Utilize CP members to provide information exchange to enhance collaboration and identify further engagement topics/issues.				
Community Partners	Identify potential contacts for information exchange. Increase awareness of CP training materials. Promote CP training materials at full network group meetings.	Identify potential contacts for information exchange and enhance collaboration and identify further engagement topics/issues.	Ongoing	A Community Partners presentation was featured during the 2011 HPTN Community Working Group Meeting in DC. An overview of the CP Training Materials was presented to HPTN staff and CAB representatives. A CP Training Materials Train the Trainer Session was facilitated for participants attending the 2011 HPTN Annual Meeting. Community Partners continues to work with the TB Alliance and other partners to develop tools to measure the impact of Community Engagement on clinical research. Community Partners is in the process of collaborating with DAIDS on the formation of a TB Working Group. Increased collaboration with other HANC coordination areas to enhance the overall mission on Community Partners.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Implement Information Technology Best Practice Standards developed in Year 3 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 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. The Task Force reviewed results from the site survey and shared an executive summary with DAIDS and network leadership. The survey outcomes have informed the updating of the Best Practices document.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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.	Q3.	Facilitated conversation amongst cross-LIMS partners. Determined feasibility and timeline for implementation. Resolution expected by the end 2011. Created information dissemination plan and protocol for system changes.
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: Harmonization of 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 ad hoc reviews with DAIDS-affiliated clinicians. Hosted a F2F meeting at the June 2011 IMPAACT FGM.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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. Invited OPCRO Acting Director Scott Proestel to a WG call to discuss DAIDS' thoughts around using CDISC reporting standards. The DMCs will collate and share a consensus statement addressing DMC data harmonization concerns. DMC members have participated in discussion to harmonize behavioral elements in network studies. Drafted and shared a "MedDRA Implementation Working Group Charter" for DAIDS/RSC review.
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 Leaders' 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. Submitted an updated "SAE/EAE Reconciliation" policy to DAIDS for review. Submitted a "DMC Consensus Statement on Safety Issues" to DAIDS for review and discussion.
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.	Ongoing opportunity to discuss experiences using DAERS on monthly and ad hoc conference calls. HANC attends the monthly DAIDS-ES team call.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #9: Consider hosting a one-day DMC face-to-face meeting. DMC representatives will use the time to present ongoing intra-DMC projects and consider additional areas of coordination.				
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. The group is exploring the feasibility of hosting a F2F meeting when CROI meets in Seattle in March 2012.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Understand the processes for protocol development and implementation in the DAIDS HIV/AIDS networks.				
Evaluation Measurement Task Force	Model time to event data across protocol development and implementation milestones, from concept proposal to study completion and publication of the primary analysis.	Shorten protocol development implementation process where possible.	Ongoing.	The DAIDS-ES team has provided an updated data set. The WG is refining the parameters of the analysis and completing the missing data from the data extracted from the DAIDS-ES database. All protocols in development or open at the time of the start of the current funding cycle will be included..
Objective #2: Determine if and how harmonized processes and collaboration are contributing to improved communication, information sharing, and study implementation across the HIV/AIDS networks.				
Evaluation Measurement Task Force	Using a broad set of measures with which there is experience in the networks, as well as focus groups and structured interviews (e.g. CRS leaders, site coordinators) analyze the performance of single network vs. multi-network affiliated clinical research sites (CRSs).	Identify similarities and differences in the management, funding and performance of multi- vs. single network NIAID clinical research sites.	Q3 2012	CSI has been working with Christie and the ad hoc WG to put together a survey to understand the issues with working with pluripotent or multi-network sites. A draft survey has been developed to identify the benefits and challenges of working at pluripotent sites. The WG has held 1 call this quarter to review the survey. The Ad Hoc Working Group is also trying to make the language consistent, and better understand who the primary point of contact is at each site. Discussion also continues on how to determine the structure for communications and how the survey should be disseminated. Scott Rosas and Marie Cope from CSI spend a day in Seattle meeting with the HAN team on August 22, 2011 to discuss all ongoing and planned evaluation projects.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Assess the scientific output and impact of the scientific the DAIDS networks relative to current scientific literature, practice guidelines, continuing medical education, and networks' own scientific agendas.				
Evaluation Measurement Task Force	Conduct a five-year bibliometric data analysis for longitudinal assessment of translational scientific impact of network research.	Objective evaluation of the impact of the research output of the NIAID HIV/AIDS Clinical Trials Networks.	Q4 2012	In Q2, HANC will collect from the Networks all publications from 2009-2010 and data cleaning will begin for the next bibliometric analysis.
Objective #4: Understand the nature of involvement and the impact of community members' participation in network protocol development and implementation, and the relationship to the perceived community relevance of network research.				
Evaluation Measurement Task Force	Conduct an analysis to identify and profile best practices in community involvement across networks.	Identify evaluation methodology and the impact of community participation on the Networks' scientific agenda and protocol development process.	Q4 2012	The revised Community Partners/CAB Site Survey was launched and is currently open. Participants have until October 8, 2011 to complete this survey so that it can be done during their regular CAB meetings. Several completion reminders for the survey were sent in Q1.

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.				
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; Q2 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 2 sets 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 2 calls during which the group: Reviewed and provided feedback on demonstration of new PTPT System Agreed on plan to distribute GCLP documents Reviewed laboratory training listing on HANC public website and agreed on plan for distribution of notice Received an online tour of the resources available on the CRS Partners site and provided feedback

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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	<ul style="list-style-type: none"> Regularly updated page about ordering fetal bovine serum Regularly updated VQAAB reports and minutes Posted guidance for PBMC laboratories Developed and populated VQA Laboratory Status and Laboratory Contact lists Updated PNL Assignments list
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 data and records in database.
HANC Support Staff	Upgrade Proficiency Testing Performance Tracking (PTPT) System	Provide a streamlined, user-friendly tool for the network laboratory managers to collect and summarize feedback from all affiliated networks when there is a proficiency testing (PT) failure at a site laboratory.	Q1 Upgrade PTPT System, demonstrate to users and collect feedback, build out network dashboard pages, finalize system and launch.	This project was functionally completed in Q1. One outstanding task is to fix the automatic reminders.
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. The TQM Program will improve the transparency and responsiveness of decision-making regarding results of proficiency testing at DAIDS-funded site laboratories by improving communication and timely access to relevant information.				
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 1 call during which the group: Reviewed updates to the performance summary Finalized CD4/CD8 Method Validation Guidelines
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).	<ul style="list-style-type: none"> Reviewed preliminary results comparing automated to manual counts at the IQA Reviewed some preliminary results comparing viability and viable recovery of thawed cells before and after resting

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
ICAG	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA PBMC labs.	Consistent quality control of IQA PBMC cryopreservation testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 4 calls during which the group reviewed proficiency testing summaries and resolved specific laboratory issues.
ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository.	Reliable results in functional and phenotypic assays.	Q1-3 Collect and analyze additional samples, evaluate results	This project was on hold during Q1 while the IQA collects and tests additional samples.
ICAG	Consider the feasibility of using functionality data from researchers to determine the quality of similar samples stored at the BRI repository.	Reliable results in functional assays.	Q3 Initiate a pilot study; Q4 Submit example data to statisticians for review and recommendations	<ul style="list-style-type: none"> • Clarified questions the group would like to use the functionality data to answer • Defined a data collection schema for the collection of all the necessary data • Initiated a pilot program between FSTRF and two pilot labs for the collection of the necessary data • Received presentation from EQAPol regarding the effects of long-term storage in liquid nitrogen on functionality • Clarified how calculations of viable recovery should be performed
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; Q3 Post	On hold during Q1
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.	<p>Held 1 call during which the group:</p> <ul style="list-style-type: none"> • Received updates from the CPQA and the networks • Discussed the addition of TB drugs • Learned about the new lab structure of the ACTG

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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: <ul style="list-style-type: none"> Received updates from the CPQA Provided feedback on the online AVR/SOP submission utility Discussed assay complexity scoring for lab evaluation
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.	This group was on hold during Q1.
Virology Quality Assurance Advisory Board (VQAAB)	<ul style="list-style-type: none"> 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 2 calls during which the group: <ul style="list-style-type: none"> Reviewed PT reports and cumulative performance summaries Received updates on the 200 copies/mL control
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.	Q1 Apply new formatting to standard wording templates; Q2 Finalize	Applied new formatting to approximately half of the standard wording templates
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.	Q1 Perform final review and post	<ul style="list-style-type: none"> Distributed SOP to group of final reviewers and collected feedback Held one call to review feedback and finalize SOP Posted SOP, worksheets and templates on HANC public website
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.	Ongoing: populate library, assist users, monitor work flows	<ul style="list-style-type: none"> Provided updates to network laboratory groups to solicit missing certificates Assisted users and monitored work flows Added drop-down menu options as necessary

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #4: Continue collaborating amongst the Networks, HANC, DAIDS and SMILE to improve TB Laboratory, 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: <ul style="list-style-type: none"> Review validation plan for Microbank tubes and provide feedback Review and approve SOP for infection control at clinic sites; determine next steps for network/DAIDS implementation Receive update on development of an international TB specialty lab
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 Q1.	<ul style="list-style-type: none"> Initiate the process of standardizing sputum collection and decontamination assays; collecting assays from partner organizations
Objective #5: Collaborate among the networks, HANC, NIAID, Patient Safety Monitoring in International Laboratories (SMILE) and other organizations to establish and improve malaria diagnostics capabilities and procedures and quality assurance for participation in network and non-network studies with malaria diagnostics endpoints.				
Malaria Laboratory Working Group	Survey existing malaria diagnostics technologies.	Establish common understanding of existing malaria diagnostics technologies, their strengths and weaknesses, and the feasibility of using each in clinical and research settings.	Q1 Complete survey	Held 2 calls during which the group heard presentations and reviewed: <ul style="list-style-type: none"> The use of microfluidics to develop point-of-care diagnostics Two automated slide reader systems that are in various stages of development/validation

Legacy Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Continue to increase partnerships and collaborations with government agencies, scientist, CBOs and ASOs, medical/academic institutions, specialized institutions/networks, experts/advisors.				
Legacy Project Staff	<p>The Legacy Project will increase the number of formal partnerships with governmental agencies, including but not limited to, six Health Departments; 24 CBOs and ASOs, specifically collaborating with 14 African-American and 10 Latino-focused organizations within the US; two additional NIAID networks, specifically MTN and HPTN; four Historically Black Colleges and Universities (HBCUs); faith-based organizations, the house/ball community and the arts and culture sector.</p> <p>The Legacy Project will establish two new subcommittees of the Legacy Project Working Group, specifically a Membership Workgroup and Research/Evaluation Workgroup.</p> <p>Legacy Project will host two F2F meetings, including the Legacy Project Workgroup and the Women’s HIV Research Collaborative.</p>	Increased partnerships and collaborations among sites, governmental agencies, CBOs/ASOs, community groups and key leaders.	Ongoing	<ul style="list-style-type: none"> The Legacy Project has initiated engagement with 5 city and 3 state health departments; started conversations with 9 CBOs and ASOs (Black AIDS Institute, National AIDS Education Services for Minorities, MOCHA, Black Gay Research Group, National Gay Men’s Advocacy Coalition, African American Young Men Who Have Sex with Men Working Group, South Carolina HIV/AIDS Council, Latino Commission on AIDS, Reach LA); collaborations with MTN and HPTN are in progress. Legacy has initiated a partnership with the Adolescent Medicine Trials Network (ATN); Legacy has a pilot project with Lincoln University as lead, that will include 9 other historical Black colleges; Legacy initiated engagement with Latino faith-based organizations as well as members from the arts and culture community. Legacy is collaborating with Emory University on the development of joint programming. Legacy will roll out 4 new subcommittees of the Legacy Project Working Group (LPWG) in Q2, including: Membership; Research and Evaluation; Engagement and Collaboration; Capacity Building and Technical Assistance. Pre-planning has begun for the Women’s HIV Research Collaborative (WHRC) and LPWG face to face meetings in March 2012.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Influence the creation of scientific agendas and science that is responsive to community priorities. Conduct and support primary research on community engagement and clinical trial participation and the relationship between them.				
Legacy Project Staff	<p>The Legacy Project will hire a Social Scientist at .5FTE.</p> <p>The Legacy Project Social Scientist will conduct an analysis on representative enrollment in HIV clinical trials.</p> <p>The Legacy Project will submit 2 abstracts at national conferences for peer-review on evaluation activities, 2 grant proposals for program expansion activities and research initiatives, and 2 manuscripts and/or journal articles.</p> <p>The Legacy Project will establish a speaker's bureau that will include 6 scientists to disseminate advances in HIV clinical research.</p> <p>The Legacy Project will work with the Research/Evaluation Workgroup and the Women's HIV Research Collaborative to identify community research priorities.</p>	<p>Increase scientific literacy and access to accurate and relevant scientific information among sites, governmental agencies, CBOs/ASOs, community groups and key leaders.</p>	Ongoing.	<p>Michael Arnold (PhD, MPH, MSW) joined the Legacy staff as a Social Scientist on July 5, 2011. A concept proposal for a study on differential representation across networks was prepared for submission to the Network Leadership Group in September 2011.</p> <p>The following abstracts have been submitted: <i>Best Practices for Engaging MSM at Black Pride Events</i> (submitted to LGBT Health Summit (accepted); submitted to Unity through Diversity Conference (accepted); <i>Engagement, Recruitment, and Retention</i>: (submitted to LGBT Health Summit (accepted); <i>Translating HIV Vaccine, Microbicide, and PrEP Trial Results for Prevention Educators</i>; submitted to USCA (accepted). <i>What's Next and What's Needed With HIV Research with United States' Women?</i>; submitted to USCA (accepted).</p> <p>A grant proposal on economic conditions and HIV behaviors among low-income Black, Latino and White young MSM is being developed for submission to NIH R01 funding in Q3. A second proposal assessing approaches for HVTN clinical sites to identify and improve approaches to recruitment and retention of under-represented populations will be written in collaboration with the HVTN Social Scientists in January 2012.</p> <p>A third proposal, <i>Voices and Soul Tapestry Project</i>, collaboration between Legacy and Emory University, has been developed and will be submitted in Q2. Additionally, there were two grants written in Y5, but were funded in Y6 Q1; which are <i>Be the Generation Bridge Project</i> and <i>Native American Engagement in HIV Clinical Research</i>.</p> <p>The Legacy Social Scientist actively participates in the HANC Behavioral Science Working Group. The Legacy Community Engagement Officer and Legacy Project Director actively participate in the Women's HIV Research Collaborative.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Build the capacity of communities and researchers to equally partner in the research enterprise.				
Legacy Project Staff	<p>The Legacy Project will develop and pilot test a cultural awareness and community engagement curriculum and/or tool kit for HIV/AIDS clinical research sites, scientist and community groups.</p> <p>The Legacy Project will develop 2 fact sheets and/or white papers, one on overcoming barriers with racial ethnic groups and the second focusing on engaging transgender populations within the US.</p> <p>The Legacy Project will host 4 webinars on overcoming barriers to HIV prevention and treatment clinical research, engaging MSM, and identifying women’s research priorities and new prevention techniques.</p> <p>The Legacy Project will host a minimum of 12 workshops/presentations at conferences and other meetings to improve community research literacy and the capacity of HIV clinical research sites, community advisory boards and/or researchers.</p>	<p>Improve the capacity of sites, governmental agencies, CBOs/ASOs, community groups and key leaders to overcome barriers to participation in clinical research through engagement, mobilization and education among disproportionate populations.</p>	Ongoing	<p>The Legacy Project is in the process of developing a basic curriculum to be refined through community engagement. This curriculum will be tailored for NNAAPC, LETI and the BTG projects in Q2 & 3. A toolkit has been developed for local clinical sites to engage Black MSM during Black pride events.</p> <p>Fact sheet development is forthcoming; one white paper on overcoming barriers to participation in clinical research based on collaboration with the Black Gay Men’s Network retreat in the Dominican Republic in Q2.</p> <p>The WHRC is planning a webinar on PrEP and implications for women in emerging HIV-related clinical trials.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #4: Enhance the internal and external operations of the Legacy Project.				
Legacy Project Staff	The Legacy Project will develop a comprehensive communication plan as well as a staff professional development plan. The Legacy Project will rebrand to include: logo re-design, letterhead and product design.	Increased visibility, procedures and processes for Legacy staff to improve clarity and expectations around roles and responsibilities.	Ongoing	Individual professional development plans will be developed in tandem with annual performance reviews in Q2. Logo redesign is in process; rebranding strategies are in development. The Legacy Project Strategic plan was refined in Q1 and will be presented to the Legacy Project Working Group for review and adoption in Q2.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) was originally charged with implementing and advancing optimal collaborative clinical trials research activities among the NIH-sponsored HIV/AIDS clinical trials networks. NLOG calls include the participation of representatives from 18 NIH Institutes and Centers and provide a venue for cross-network as well as cross-institute information sharing and discussion. HANC solicits information from the networks, NIH representatives and other partners to bring forward and organizes and facilitates quarterly teleconferences. The NLOG group met on July 27, 2011 in Q1 and heard a presentation from Craig Wilson reviewing the structure and scientific agenda of the Adolescent Trials Network. A poster on the network bibliometric analysis that was presented at the 6th IAS meeting in Rome, Italy on July 19, 2011 was also reviewed on that call by Jeff Schouten, the poster presenter.

The AIDS Clinical Trials Network Strategic Working Group (SWG) is a working group of ARAC that is intended to provide strategic review and planning for the coordinated research efforts of the NIAID HIV/AIDS Clinical Trials Networks. The SWG provides input on strategic issues that cut across all six HIV/AIDS clinical trials networks, including overall priority setting for research plans, assessment of research opportunities and coordinated strategic planning across the networks. The working group is convened 3-4 times a year by DAIDS to review and discuss scientific plans, progress and opportunities, specific protocols and cross-network issues. The HANC director participates in the SWG but the group is organized and facilitated by DAIDS. The SWG did not meet in Q1 as they met in May 2011.

HANC organizes focused monthly and ad hoc conference calls with the six network Principal and Co-Principal Investigators to address cross-cutting network leadership issues. The Network Leadership Group met 3 times in Q1. Topics discussed included a presentation and discussion with by Hugh Auchincloss, NIAID Deputy Director, on the regulatory issues in protocol reviews in India on the August 2011 call; new projects developed by the Legacy Project were focused on during the September 2011 NLG call. HANC and DAIDS leadership also hold monthly conference calls to collaboratively identify and address issues and share updates on activities. DAIDS Leadership-HANC calls were held on June 24, July 29, and August 8, 2011 in Q1. HANC also holds a monthly call with the leadership of OCSO and a bimonthly call with OPCRO leadership.

The Seroconverters Study Group is an ad hoc group first convened at the request of the Network Leaders Group in February 2011. The purpose of this group is to first compare and contrast the objectives and schedules of events of the various network and non-network protocols that follow study participants who seroconvert during HIV prevention trials. The group will also consider the feasibility of harmonizing the approach to following seroconverters across networks and develop recommendations for the Network Leader's Group.

Site Management & Logistics Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Work closely with network staff and DAIDS to review the harmonized network Conflict of Interest/ Financial Disclosure requirements 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.	Ongoing.	The SOP was approved by Network Leaders in Q4 of Y4. The WG is in discussions with a developer to create a cross-network online reporting system. WG is review new HHS rules and monitoring Federal guidance and related assessments.
Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS officers 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 two calls with OCSO. OCSO has indicated interest in providing input on the development of the pluripotent site survey (see evaluation objective #2).
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.	As part of the restructuring conversations, NIAID has emphasized a desire to develop more potent CTUs supporting more centralized operation issues. This WG has begun looking for opportunities in harmonizing policies and procedures for central labs, pharmacy, SDMCs etc. Discussions around significant differences in policy and procedures across the networks, and how to best harmonize these took place. Ana Martinez, R.Ph., Chief, DAIDS Pharmaceutical Affairs Branch has been invited to join a future call to join in these discussions. The WG also provided feedback on the newly revised DAERS training website. The DAIDS ON TRAC WG also asked for feedback on the draft DAIDS Training resources flier.
Objective #4: Convene a sub group of site coordinators to consult on the Pluripotent Configuration Study project (see Evaluation Objective #2)				

Training Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Identify and provide access to cross-network standardized training for high priority topic areas.				
Training Committee	Identify and discuss training needs and ways to provide access to trainings. Use HANC portal team site for information sharing, training announcements, training requests, and document development.	To address training needs.	Ongoing.	The Committee provided feedback on the newly revised DAERS training website. The DAIDS ON TRAC WG also asked for feedback from the Committee on the draft DAIDS Training resources flier. Updates were provided on the Training Needs Assessment Tool that is being piloted to sites, the DAIDS Regional Training Event that took place in to take place May 2011, in Durban and modules under development to be released in the DAIDS LMS. An overview on the recommendations for the structure of CTU/CRS at NIAID council was presented to the Committee which started discussions on how to best prepare and harmonize for the recompetition. The CP Ethics WG presented their work of looking into developing a cross-network training module around the issue of the Informed Consent Process and asked for feedback from the Committee when needed. The HRCT closing project updates were provided and all networks were asked to regularly remind their site staff about the curriculum. Marketing input was also received from the Committee. Lastly, safety training topics available for upcoming network meetings were presented by Dr. Ling Chin and all were asked to submit training requests via the HANC Training Request Mechanism in a timely fashion.
Objective #2: <i>See Community Coordination Objective #2.</i>				