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Infrastructure and Administrative Support

The HANC Public Website

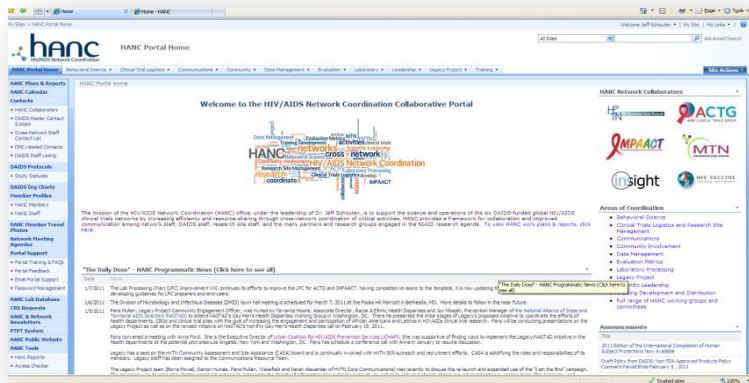
The HANC public website (www.hanc.info) contains a calendar of events, network newsletters, general information about HANC’s coordination activities, training resources, laboratory resources, and other resources for collaborators, research sites, and the general public, including:

- 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 VOICE, 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. Users can filter by network or type of intervention, zoom in or drag to see sites in their area, and view site contact details.
- 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.
- A library of links to network websites and social media communication resources.



Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
HANC & IT staff	Public site updates and rebranding project.	Improved capacity, ease of navigation flow, resources, and access to information.	Ongoing.	HANC is in process of implementing phase III 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 . In Q3 staff worked on a page dedicated to the network online sites and social media presence as well as a dynamic, searchable map of network clinical research sites around the world. HANC exported site geocoordinates from the DAIDS-ES, researched and added latitude and longitude for approximately 375 of 590 sites, and submitted the updated data to DAIDS for inclusion in the ES.

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 Q3 we added a net of 4 new portal users, for a total of 1,028 active HANC portal user accounts and 5 new secure team sites for a total of 72 team sites that 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 Q3
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 Q4.
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.	Q3.	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 early Q4 with re-establishment of the DAIDS-ES data connectivity.
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. Developed and posted a series of SharePoint training documents. Ongoing development "HIV/AIDS Protocol Milestone Calendar" with AVAC.
HANC staff	Development of Lab Groups sub-site on HANC public website.	Provide information about lab group activities and reach out to potential members, as appropriate.	Q2 Complete structure and begin content; Q3 Complete.	Updated laboratory group structure and activities information.

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 publishes the newsletter monthly. HANC has made an effort to "friend" or "follow" research partners and related advocates so as to help circulate news and network updates. "HANC Portal 101s" and SharePoint tutorials are now offered on an ad hoc 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 Q3
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. HANC coordinated travel/accommodations for ~20 Black Gay Research Group Summit Scholars and is in the process of planning sessions at the upcoming HPTN and IMPAACT full group meetings. HANC participated in the NIH Focused initiatives for Healthier Lifestyles by the Inter Network Advisory Group on Adolescent Prevention meeting. Discussions at that session resulted in the formation of the HANC-facilitated Youth Prevention Research Working Group (YPRWG).
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	Maintain 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 834 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. BSIG members are encouraged to circulate their work, funding opportunities, and relevant research.
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 group has reviewed network CRFs and BSS elements, statistical modeling, validating qualitative measures, and ACASI on calls/webinars. This topic has been discussed on the 2012 BSWG Meeting Steering Committee calls as a priority if the group decides to pursue a cross-network BSS agenda.

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 Q1 Year 7.				
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 circulated reports from the 2011 BSWG F2F, Risk Assessment (RA) Focus Group, and Neurocognitive Assessments Focus Group. The Neurocognitive Focus Group is exploring the feasibility of producing a white paper and may be considered for publication. HANC is collaborating with USAID and DAIDS to advance the field of Risk Assessment. HANC staff attended the USAID/IAVI sponsored Sexual RA satellite at the September AIDS Vaccine Conference in Bangkok and participated in the RA-focused DAIDS BSS Workshop Organizing Committee. HANC participated on all five of the affiliated WGs and the Organizing Committee. The Organizing Committee hopes to have a publishable statement in Y7. The 2012 BSWG Meeting Steering Committee has been convened and discussed priority areas. The BSWG solicited abstracts and hopes to have a publishable paper resulting from the discussions. HANC began the process of planning a face-to-face meeting for the YPRWG before CROI 2012.
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. DAIDS, NIMH, NIDA, and ATN representatives have joined the 2012 BSWG Meeting Steering Committee and/or Abstract Review Committee. The YPRWG features representatives from the DAIDS networks, the ATN, NIAID, NICHD, NIDA, NIMH, and OAR.

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. Recently, the BSIG has reviewed community viral load in San Francisco and the “Be the Generation – Bridge” Projects, support strategies for biomedical HIV-prevention product use in clinical trials, network CRFs and BSS elements, statistical modeling, HANC staff expects to host webinars on behavioral incentives, the HIV epidemic in young women in sub-Saharan Africa, and the measurement of viral load in Vancouver BC in Q4.
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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.	The WG has discussed implications resulting from FEM-PrEP, HPTN 052, HPTN 058, and VOICE trials. 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. HANC created a webpage to highlight the networks’ websites, protocol-specific websites, and social media identities.
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 continued with NIH’s InCommon project and Internet2 consortium members 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. The group has hosted four calls to date and HANC staff has contacted US institutions that have adopted the model. HANC is working with AVAC to create a robust “protocol milestone calendar” which will live on the HANC portal’s Communications Resource Center. The resource will allow users to review important time points (e.g., DSMB reviews, expected full accrual dates, major conferences and presentations, etc.) in HIV/AIDS clinical trial research conducted around the world.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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, CDC, 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. HANC added design tool and links to design guides on the CRC.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #4: Share IT- and communications-related developments across all areas of coordination.				
HANC Staff	<p>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.</p>	Improved communication across networks and HANC activities.	Ongoing.	<p>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. Q2 calls addressed HANC and network social media projects, major trial results communications plans, preparing for DSMB reviews, 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 meets monthly to discuss issues that cut across the community, behavioral science, communications, training, site coordination, Be the Generation Bridge, and Legacy Project areas of coordination. HANC launched the interactive DAIDS network site map and encouraged Ops center and site staff to use the filterable display to help relocate participants, etc.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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. The group discussed strategies to encourage use of collaborative websites and the value of protocol-specific websites. The group continues to discuss evaluation metrics and 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. The WG discussed community input related to the utility of network-generated communications materials meant for staff and the general population.
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. HANC has worked with AVAC to create a Social Media WG. HANC submitted an abstract and was accepted to present at Sex::Tech 2012, a conference dedicated to sexual health of adolescents and new media. The topic will be the Communications WG's efforts to leverage collective expertise through collaboration. HANC contributed to the AVAC social media survey circulated to research and advocacy group and is a named speaker on the AVAC abstract submission for the IAS 2012 Global Village presentation. Notification expected Q4.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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's "Communications Topics of Interest Webinar Series" has continued with discussions of using Facebook and graphic design for the web. Upcoming topics include the CDC Social Media Handbook, graphic design for print, and Twitter. HVTN's Soyon Im presented on developing mobile websites for research recruitment. The series is open to network operation center and site staff as well as community members.
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.	Completed.	The WG decided to postpone a gathering until further notice.
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. DMCWG working with DAIDS to update the "Topic-specific DAIDS Contact List".

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	<ul style="list-style-type: none"> 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 to present to DAIDS 	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. Develop questions to make the current priorities more detailed and specific.	Completed evaluated research gaps and are currently developing specific research items/concerns Ongoing.	The group is using a grid concept for each research priority to identify more specific research issues/questions. The group is currently working to convert the research list into a draft prose document as part of its Year 7 Work Plan, the group has proposed collaboration with other community based groups and coalitions to advance HIV/AIDS-related community based research priorities and issues through CP's unique relationship with, and access to DAIDS, the clinical trials network leadership and network-associated community groups/advisory boards.
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 	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 developed two eLearning modules based on the CP Training Materials that are currently available on the DLMS. The group developed a flyer to promote the CP Training Materials at various events and meetings. The group has contacted non-DAIDS ASOs and CBOs with the aim of promoting 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 Q3
	<p>research participation.</p> <ul style="list-style-type: none"> • 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, • Gather and catalogue available training resources on the HANC website. 			
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. • Develop and administer 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. • Revise the Site Staff and Site CAB survey • Disseminate survey results and use findings to help guide future 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 submitted a manuscript based on the results of the CP 2010 survey. The manuscript was accepted in February 2012 by Progress in Community Health Partnerships: Research, Education, & Action for a theme issue on the "Science of Community Engagement." Held joint conference calls with the Site-Level Funding Working Group to discuss preliminary results of the 2011 CP Survey. Created and administered a survey for the purpose of evaluating the impact of CP activities.

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. 	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 the CP site-level funding WG formed a writing group, as noted in Objective #2, and the paper was accepted for publication in February 2012. Held joint conference calls with the Evaluation Working Group to discuss preliminary results of the 2011 CP Survey.
Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming network restructuring.				
Community Partners	<ul style="list-style-type: none"> • Solicit input from networks and other interested groups to provide input and recommendations to DAIDS regarding the Network recompetition and restructuring process. • Share CP FOA recommendations with CABs and Site staff 	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 the ATN as part of the NIAID restructuring process. Drafted agenda for a 2012 CP F2F Meeting. In the process of drafting abstracts for submission to USCA 2012.

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	<ul style="list-style-type: none"> Identify opportunities for improvement and work in collaboration with DAIDS to provide guidance in developing and updating DAIDS informed consent assessment documents and processes for supported and/or sponsored protocols. Collect, review and analyze information related to management of pregnancy and contraception on study to identify and generate related cross-network tools and guidelines/recommendations Provide cross-network input to DAIDS to support the development of ethical guidelines and considerations into trial designs. Identify opportunities for improvement and generate recommendations regarding placebo arms in prevention trials. 	Identify areas where there are problems or opportunities for improvement to address these issues.	Ongoing	Collected network and site IC assessment tools and processes. Reviewed and analyzed current IC assessment tools and processes. In the process of identifying and generating related cross-network tools and guidelines or recommendations to ensure that international sites are included. Focused on generating recommendations to be used for updating current IC process and IC assessment of understanding practices/tools.

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 Gather and organize existing network CAB newsletters to post on the HANC website.	Identify potential contacts for information exchange and enhance collaboration and identify further engagement topics/issues.	Ongoing	<ul style="list-style-type: none"> 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. Community Partners is in the process of collaborating with the ATN specifically around the issue of community engagement. As part of this collaboration, a member of the ATN has agreed to present at the June CP F2F Meeting. 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 Q3
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.	Completed.	Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. The IT Best Practices Document Task Force reviews 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. In Q3, the Task Force finalized, posted and circulated notice of the Best Practices document. In future, the Task Force will meet on an ad hoc basis to address needed updates or questions posed by the network sites.

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.	Q4.	Facilitated conversation amongst cross-LIMS partners. Determined feasibility and timeline for implementation. Final testing and system updates are nearly completed. Resolution expected by mid-Q4. 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.	Mappings have been completed. SDAC coders have created and circulated documentation as well as demoed the tool internally. HANC will help circulate notice of the tool and host a series of "brown bag" webinars for interested researchers. The WG will present the tool at the upcoming ACTG and IMPAACT full group meetings. MedDRA upversioning is underway and the WG has contacted the DAIDS-facilitated MedDRA Implementation WG's (MIWG) MedDRA consultant can assist with reviews.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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. The WG continues to discuss CDISC implementation and are preparing questions related to adoption of the data standard as noted in the network RFAs. DMC members have participated in discussion to harmonize behavioral elements in network studies. Confirmed adoption of the "MedDRA Implementation Working Group Charter". The group monitors the recently finalized "Appendix 100" which merged ACTG and IMPAACT clinical code appendices. Discussed ways to improve the DAIDS-ES format and communications with product champions. HANC is now soliciting, collating, and sharing DAIDS-ES Collaborator Call agenda items/change requests with DAIDS representatives. The group discussed ES contact list updates, communications, etc. with DAIDS-ES Business Manager on a recent call. DMC members have been participating in the SSO discussions, which, if the model is adopted, could harmonize network member login credentials for participating portals and websites.
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. Updated the DMCs on changes to protocol template consent language noting that trial results will be public on clinicaltrials.gov.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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. Updated reports are posted to the HANC public website on a recurring basis. HANC disseminated DAIDS-issued memos. Confirmed that the updated "SAE/EAE Reconciliation" procedure has been adopted though a formal policy will not be issued by DAIDS.
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.
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 adding a DMCWG meeting to the end of a data management training session.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 of all protocols in development or open at the time of the start of the current funding cycle (n=111). The WG is refining the parameters of the analysis and completing the missing data from the data extracted from the DAIDS-ES database and adding projected and actual accrual targets.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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-Q4 2012	The Site Coordinators WG Beta tested the survey and determined it was difficult to answer some of the questions since the survey seemed to assume that resources are being shared across the networks and that the survey seemed to compare single vs. multi-network sites. Based on this feedback, CSI and HANC will work on making necessary changes in order to capture information more clearly. It was also noted that collecting qualitative information may be more beneficial. How to best disseminate the survey will be determined once a survey is in final form.
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 – Year 7	HANC is collecting from the Networks all publications from 2009-2010 and data cleaning began 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 has been closed and data analysis is underway. Four of six networks are interested in collaborating on one CAB survey for all of the networks to use in order to streamline the survey and cut down on how many surveys CABs and sites are asked to complete. The feasibility of creating such a survey continues to be discussed within each of the networks.

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	Updated the LT Workload Tracking System with current protocol and lab tech information in an ongoing manner.
Cross-Network Lab Interest Group	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 3 sets of laboratory 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	<p>Held 4 calls during which the group:</p> <ul style="list-style-type: none"> • Discussed labs that receive DAIDS visits; • Planned a survey of labs that use the Abbott m2000 and reviewed the results, determining that Abbott was meeting needs on a case-by-case basis; • Agreed to review and revise the Guidelines for Communication and Data Flow for each EQA program; • Developed a plan for alternative EQA at sites with multiple clinic labs with DAIDS and SMILE representatives; and • Developed a plan for protocol analyte reviews with DAIDS and SMILE agreed that the Primary Network Lab will continue to provide IATA training materials for each lab; • Reviewed the new CRSS contract and how it affects lab audits and training with DAIDS, SMILE, FHI360 and Westat; • Agreed to retire the Proficiency Testing Performance Tracking System; • Agreed on a frequency for the review and revision of the Cross-Network PBMC Processing SOP; • Approved HANC’s proposal for reorganizing the HANC-coordinated lab groups; and • Reviewed and revised the group’s annual goals.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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; Regularly updated VQA Laboratory Status and Laboratory Contact lists; Added information about the Malaria Lab Network; and Updated information about each group and structure of HANC-coordinated lab groups.
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.
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.	Held 1 call during which the group reviewed updates to the performance summary and agreed to hold calls on an as-needed basis instead of monthly.
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.	<ul style="list-style-type: none"> Held 2 calls during which the group: Reviewed proficiency testing summaries; Determined how best to accommodate ACTG/IMPAACT-iPrEX multi-affiliated labs; Reaffirmed that labs receiving a PA status cannot resubmit samples to improve their scores, although they may resubmit for troubleshooting purposes; and Reviewed and revised annual goals.
ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository.	Reliable results in functional and phenotypic assays.	Q1-4 Collect and analyze additional samples, evaluate results	This project was on hold during Q3 while the IQA collects and tests additional samples.

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 the BRI repository.	Reliable results in functional assays.	Q2 Develop reporting system	<ul style="list-style-type: none"> • FSTRF worked with pilot testing labs and the ICAG to develop reporting system; • The ICAG agreed to form a temporary working group to develop a reference guide for submitting labs and FSTRF; and • The ICAG reviewed a comparison of PBMC thawing/resting SOPs prepared by HANC staff and agreed to ask the LTC to develop an SOP for the ACTG/IMPAACT Lab Manual based on the IQA's thawing SOP.
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.	Q4 Initiate review and revision	On hold during Q3
ICAG	Consider the use of Day 1 viability and viable recovery data in performance criteria	Align proficiency testing procedures more closely with patient sample procedures	Q3 Decide whether or not to use Day 1 viability and viable recovery data.	The group agreed to continue to use Day 0 data only.
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.	<ul style="list-style-type: none"> • Held 1 call during which the group: • Reviewed international pharmacology lab assessments; and • Received network and training updates • Discussed the formation of a new Biological Matrices Working Group
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.	<ul style="list-style-type: none"> • Held 2 calls during which the group: • Discussed special panels for testing hemolyzed, & lipemic samples, and for testing drug stability; • Reviewed updates and suggestions for the AVR/SOP Online Utility; • Reviewed updates to policies & procedures, training, and manuscripts; • Reviewed the new CPQA Panel Participation Utility; and • Discussed needs for capturing data for intracellular assays.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 the network recompetition and how it will affect the pharmacology labs and what is needed from the CPQA.
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.	<ul style="list-style-type: none"> Held 4 calls during which the group: Reviewed PT reports and cumulative performance summaries; Discussed changing network needs with regards to the distribution of performance summaries; Discussed validation of new sequencing instruments with the ViroSeq assay; Determined that the use of CORE facilities with HIV GEN testing for proficiency testing must reflect what is done for protocol samples; Determined that laboratories using the manual Abbott extraction method as a back-up to the automated Abbott extraction method but also submit proficiency testing samples for manual extraction; and Determined that if any VQA controls are invalid in any HIV DNA (or RNA) assay, then the whole run should be deemed invalid and must be repeated. Discussed the use and validation of the Hi-Pure extraction method. Reviewed and discussed the use of Levey-Jennings control plotting, a new QC module in the LDMS, and Westgard Rules for quality control. Determined that results should be reported in the LDMS since they match the results generated by the assay.
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.				
LPC Working Group 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.	Q3 Complete first versions of each standard wording section; Ongoing: Update standard wording content	The first version of each standard wording section was completed and posted on the LTC team site.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
ACTG/IMPAACT LTC and HANC Support Staff	Update ACTG/IMPAACT Lab Manual	Standardize a variety of laboratory procedures across ACTG and IMPAACT labs; update with current information and best practices	Q3 Develop project plan; update links; convert documents and build new development library; develop SOP template; initiate revisions Q4 Continue revisions; post revised SOPs as they are completed	Updated link, converted documents to CLS format, built new development library, developed SOP template, assigned SOPs and initiated revisions.
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.	Q3 Finalize and post translations	Translations were finalized and posted.
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; and • Added drop-down menu options as necessary
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.	<ul style="list-style-type: none"> • Held 3 calls to: • Determine EQA requirements for A5295; • Discuss the WHO artificial sputum matrix validation panel for the GeneXpert; • Receive an update on the validation of Microbank tubes; • Review updates to the ACTG Infection Control Guideline and Monitoring Checklist; • Review the International TB Specialty Lab RFA; • Review a verification plan for the GeneXpert that was developed by SMILE; and • Received a presentation of a study comparing various solid culture media for TB drug trials.
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.	Q3-4 Develop standard language for sputum collection and processing	Discussed the points of sample collection and processing that have resisted standardization by the TBTC

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 Network and HANC Support Staff	Develop manuscripts for publication and posting on the HANC public website, outline the many factors that must be considering when choosing malaria diagnostics method(s) for use in clinical trials.	Provide guidance for choosing and implementing malaria diagnostics in network and non-network studies.	Q3 and Q4; Draft manuscript	HANC staff developed an outline for the manuscript. The group held 1 call during which is reviewed the outline and made a plan for drafting the manuscript. Group members worked offline to submit drafts of various sections of the document.

Legacy Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #1: Continue to increase partnerships and collaborations with government agencies, scientists, CBOs and ASOs, medical/academic institutions, specialized institutions/networks, experts/advisors.				
Legacy Project Staff	<ul style="list-style-type: none"> 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. The Legacy Project will establish two new 	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 collaborated on a MSM Statewide Conference with the North Carolina Health Department, and established formal relationships with CBOs and ASOs (National Black YMSM State of Emergency Coalition, Gay Men’s Health Crisis, Abounding Prosperity and Isis Foundation); collaborations with the Adolescent Medicine Trials Network (ATN) and the CDC. Legacy established five new subcommittees in Q3, including: Creating Awareness Through Art Advisory Group, Project Reach Steering Committee, National House and Ball Community Change Consultation Steering Committee; National House and Ball Community Change Consultation Steering Evaluation Subcommittee and the Legacy Expanded Testing Initiative Planning Group. Additionally, Legacy reconvened the Legacy Project F2F Steering Committee. The Women’s HIV Research Collaborative (WHRC) and LPWG face-to-face meetings will be held in Washington, DC, on March 19 - 22, 2012. Legacy Project will convene three additional face-to-face meetings in Q3 and Q4; including Creating

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
	<p>subcommittees of the Legacy Project Working Group, specifically a Membership Workgroup and Research/Evaluation Workgroup.</p> <ul style="list-style-type: none"> Legacy Project will host two F2F meetings, including the Legacy Project Workgroup and the Women’s HIV Research Collaborative. 			<p>Awareness Through Art (CATA), Project Reach, and the national House and Ball Community Change Consultation. The Legacy Project hosted a community event for Urban Native community members on January 5, 2012. The event brought together HVTU and ACTU site staff, Native community members and supports to learn about the NAEHCR Project.</p>
<p>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.</p>				
Legacy Project Staff	<ul style="list-style-type: none"> The Legacy Project Social Scientist will conduct an analysis on representative enrollment in HIV clinical trials. 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. The Legacy Project will establish a speaker’s bureau that will include 6 scientists to disseminate advances in HIV clinical research. The Legacy Project will work with the Research/Evaluation Workgroup and the 	<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.	<ul style="list-style-type: none"> Given challenges with securing data for this project we have decided to postpone the representative enrollment data collection. The following abstracts were submitted: HANC BSWG Meeting: Research Leading to Solutions within the House/Ball Community and Interpersonal Approaches to Engaging Diverse Communities in HIV Clinical Research (both accepted). The Legacy Project staff presented at the Black Gay Research Group Meeting (1), 2012 National AAMSM Leadership Conference on HIV/AIDS and other Health Disparities (7) and also co-hosted a lunch plenary with the MTN, HVTN and HPTN Black Caucus (1), HPTN Black Caucus Meeting (1), Creating Change (1), North Carolina MAI Community/Provider Education and Training (3). Development of the speaker’s bureau as well as speaker roles and responsibilities is in progress. A proposal on economic conditions and HIV behaviors among low-income MSM of color is being developed for submission to NIH R01 funding in Q4. A proposal assessing attitudes about HIV cure research participation among HIV positive men and women in the US is currently being developed for submission. A proposal was submitted to work with sites to identify key

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
	Women's HIV Research Collaborative to identify community research priorities.			<p>information that would be captured in screening data, HVTN Initiatives Program: Optimizing Screening Data for Monitoring and Evaluation of Community-Level Approaches to Encourage Vaccine Trial Participation</p> <ul style="list-style-type: none"> Two manuscripts on attitudes to and awareness of HIV vaccine research are underway. Additionally, two proposals were submitted to the Institute of Translational Health Sciences: Evaluation of the Native American Engagement in HIV Clinical Research Project and Understanding 'Community' as an Effective Outreach Strategy for Biomedical HIV Prevention Research with Younger Men and Trans women who have Sex with Men. A third proposal, Voices and Soul Tapestry Project, collaboration between Legacy and Emory University, has been developed and will be submitted in Q4. The Legacy Social Scientist actively participates in the HANC BWSG. The Legacy CEO and Legacy Project Director participate in the Women's HIV Research Collaborative, and work with the Legacy Project Social Scientist to develop a research project that examines differences of risk perception among women of color. In addition to the specified activities, the Legacy team has constructed a number of new survey, focus group, and interview guides assessing attitudes, strategies, and factors affecting community engagement; and attitudes and issues relating to HIV clinical research. Legacy has also developed a database to collect process, satisfaction, and inquiry data as part of BTG B Project.
Objective #3: Build the capacity of communities and researchers to equally partner in the research enterprise.				
Legacy Project Staff	The Legacy Project will develop and pilot test a cultural awareness and community engagement curriculum and/or tool kit for	Improve the capacity of sites, governmental agencies, CBOs/ASOs, community groups and key leaders to overcome barriers to participation in clinical	Ongoing	<ul style="list-style-type: none"> The Legacy Project is in the process of developing a basic curriculum to be refined through community engagement. This curriculum will be tailored for sites working with Native populations and will be disseminated broadly. A White Paper

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
	<p>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>research through engagement, mobilization and education among disproportionate populations.</p>		<p>and toolkit have been developed for local clinical sites to engage Black MSM during Black pride events.</p> <ul style="list-style-type: none"> • The Black AIDS Institute released a final report from the Black Gay Men’s Network retreat entitled, “Who I Am, Black Gay Man”; which highlights the work of the Legacy Project during a strategic brainstorming session held in the Dominican Republic in 2011. • The WHRC hosted a webinar on January 24, 2012 on recent updates from the 2nd International Conference on HIV and Women; as well as Reach LA hosted a webinar on February 27, 2012 on the findings from the national House and Ball Leadership Meeting that the Legacy Project co- led. • As noted in Objective #2, the Legacy Project hosted 13 workshops/presentations and one lunch plenary at the 2012 National AAMSM Leadership Conference on HIV/AIDS and other Health Disparities in Q3.
<p>Objective #4: Enhance the internal and external operations of the Legacy Project.</p>				
Legacy Project Staff	<p>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.</p>	<p>Increased visibility, procedures and processes for Legacy staff to improve clarity and expectations around roles and responsibilities.</p>	Ongoing	<ul style="list-style-type: none"> • Individual professional development plans were developed in tandem with annual performance reviews in Q2; while ongoing support and modification occurred in Q3. • Logo redesign is in process; rebranding strategies are in development. • Development for the communication plan will begin in Q4.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
Objective #5: Legacy Project Staff	<p>Project in partnership with fhi360 will plan and implement the Be the Generation Bridge Partnership (BTG Bridge) project.</p> <p>In partnership with fhi360, Legacy will establish a project management plan and administrative systems. Legacy Project will hire a Project Manager, Program Assistant III and Community Engagement Officer to support the project. Conduct formative research and develop process indicators.</p> <p>In partnership with FHI360, develop RFA and Select Partners. Legacy Project will conduct the scientific information and transfer trainings (SITT) and the through focused trainings, presentations at conferences/meetings, tailored capacity building and technical assistance with partners and key stakeholders.</p>	<p>A collaborative plan and processes to implement BTG Bridge. The Legacy Project will be fully staffed to plan and implement the work of the project.</p> <p>Inform materials develop and a establish a documentation process to measure the process and outcome objectives of the project.</p> <p>Select BTG partners to participate in the BTG Bridge partnership component.</p> <p>To increase partners capacity to deliver biomedical prevention programs and increase awareness and understanding of biomedical prevention of key stakeholders.</p>	<p>September 2011-October 2011</p> <p>September 2011 - November 2011</p> <p>September 2011- May 2012</p> <p>September – December 2011</p> <p>September 2011-May 2012</p>	<ul style="list-style-type: none"> The BTG Bridge Project Management Plan was written and submitted to NIAID in Q3. A literature review and stakeholder interviews were conducted and completed in Q3. The final Formative Evaluation Summary Report is in draft form and will be finalized in Q4. Process indicators for the BTG Bridge Project were developed and an accompanying access data based was developed to accurately track, store and report all program activities of SITT. The RFA was developed and released in Q2. A total of 18 partners were selected in Q3 and attended the Partner Orientation and Training that was held on January 11-13, 2012. A new RFA will be released in Q4 to select 14 additional partners. Funded BTG Bridge Partners were required to complete an Organizational Readiness Assessment in December of 2011. During the Partner Orientation and Training that was held on January 11-13, 2012, BTG Bridge Project staff reassessed organizational needs by using the data gathered from the original Organizational Readiness Assessment to ensure that needs were clearly identified. Collectively results from the assessment were aggregated and used to inform the SITT activities in Q3 & 4. In addition, BTG Bridge Project staff exhibited and presented at the Black Gay Research Group Meeting and the 2012 National AAMSM Leadership Conference on HIV/AIDS and other Health Disparities.

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 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 2-3 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 met on January 31-February 1, 2012. The HVTN presented a detailed review of the current and future research portfolio. The HPTN presented the HPTN 071 (PopART) study design.

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 had 3 calls in Q3. HANC and DAIDS leadership also hold monthly conference calls to collaboratively identify and address issues and share updates on activities. Two calls with DAIDS leadership occurred in Q3. 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 Q3
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 WG has been building across-network online reporting system for use in the 2012 solicitation. The WG has been reviewing new HHS rules and monitoring Federal guidance. The SOP has been updated to reflect the rules changes and a final version will be implemented in the upcoming solicitation. Both the SOP and the online system are expected to go live in Q4.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
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 has been reviewing new HHS rules and monitoring Federal guidance and related assessments. Updates to the SOP and web development will continue in Q3.
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 provided input on the development of the pluripotent site survey (see evaluation objective #2). OCSO also provided HANC an updated org chart posted on the website. OPCRO has been working with the RSC to provide sites with highlighted changes when revised FDA package labels are sent to the sites by RSC. This project will start out as a pilot program in order to determine the level of support effort.
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 continues 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 continue to take place. Judy Brooks, Chief, Protection of Participants, Evaluation, and Policy Branch, joined a call to share that DAIDS is updating their sample informed consent language and would like to collect feedback from this group as this project continues. This WG also beta tested the pluripotent site survey and provided excellent feedback (see evaluation objective #2). Several new DAIDS eLearning modules in the DAIDS LMS were viewed via Webinar, and an overview of changes to the Protocol Registration Manual (based on input from this WG) was provided via DAIDS during a call

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q3
				and in writing. Input was also received on the infection control survey sent by HANC to international CRS coordinators by this group. A formal report on the findings of this survey to be shared in Q4. Regular updates to the HANC website and announcements that come from DAIDS are shared on every call in an effort to bridge communication gaps. .
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 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.	Feedback and changes continue to be made to the Training Needs Assessment Tool with ongoing discussion by the network training reps. Several eLearning modules, including DAERS and the FDA Inspection process modules, were viewed with the Committee in the DAIDS LMS. The new training announcement communication plan revised to have OCSO send one announcement to all CTU and CRS PIS and site coordinators has been well received. An overview of the new CRSS contractors was provided to the committee. All new resources added to the HANC public website were viewed and asked to be shared via the Committee with relevant site staff. All are reminded to input their training requests for upcoming network meetings in the training request mechanism as soon as possible. Lastly, the HRCT limited access website was completed to help garner additional support in expanding the curriculum; this is an invite only website for collaborators external to DAIDS.
Objective #2: See Community Coordination Objective #2.				