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Infrastructure and Administrative Support

The HANC Public Website

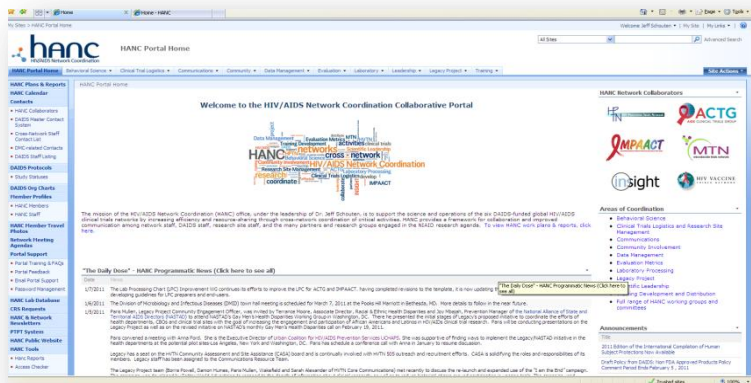
The HANC public website (www.hanc.info) contains a calendar of events, network newsletters, general information about HANC’s coordination activities, training resources, laboratory resources, and other resources for collaborators, research sites, and the general public, including:

- 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, HPTN 052, iPrEx, CAPRISA 004 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 major recent Network and other study results such as VOICE, HPTN 052 and iPrEx.
- The HANC blog as well as an easily updated program spotlight applet on the homepage: featured links to the 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 Q2
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 . Staff is currently working 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 geospatial coordinates 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 Q2 we added 11 new portal users, for a total of 1,024 active HANC portal user accounts and 67 secure team sites (2 new ones created in Q2 and 3 sites retired). The team sites are used by specific cross-network working groups for collective document development, online discussion, call calendars 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 Q2
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 and Weblog Expert 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.	Connectivity re-established in Q2, development will be completed on the user interface in Q3.	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 an upgrade we lost connectivity to the data feed in Q1. Work continued on this task throughout Q2. We hope to re-establish it in early Q3.
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 Q3 with re-establishment of the DAIDS-ES data connectivity and user interface.
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. Developing "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.	Replaced old Lab Group page with new Lab Group subsite; developed content for Malaria Laboratory Network.

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 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 Q2
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 continued to propose topics for network meetings and facilitate planning as requested and able. HANC has coordinated travel and accommodations for ~20 Black Gay Research Group Summit Scholars for their January 2012 meeting.
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 750 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 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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 2010 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 is participating in the RA-focused DAIDS BSS Workshop 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 will solicit abstracts and hopes to have a publishable paper resulting from the discussions.
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 and 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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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. The BSWG has reviewed the HIV/AIDS epidemic in US MSM, the Legacy and the “Be the Generation Bridge” Projects, support strategies for biomedical HIV-prevention product use in clinical trials, network CRFs and BSS elements and statistical modeling. HANC staff expects to host webinars on behavioral incentives, the HIV epidemic in young women in sub-Saharan Africa, and the assessment of community viral load in San Francisco in Q3.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 is creating 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-related community-based organizations to the media list and posted 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. The group hosted two calls to date and HANC staff 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. It will allow users to review important time points (e.g., DSMB reviews, expected full accrual dates, major conferences , etc.) in HIV clinical research globally.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 were 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 were 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 meet monthly to discuss issues that cut across the community, behavioral science, communications, training, site coordination and Legacy Project areas of coordination. HANC has adopted a new conference call provider and expects to cut associated costs substantially. The networks are kept abreast of the pricing and have discussed a consortium agreement that might reduce rates due to the collective call volume.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 Communications WG invited the DAIDS Scientific Communications Information Branch team on a call to discuss their work and resources. Pursued development and launch of the real-time map of DAIDS clinical trial sites. HANC is considering using Google FusionTable to display the sites on hanc.info, on participating network websites, and/or on the AIDS.gov site. The group began discussing 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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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. HPTN's Christine Rogers presented on her experience as a science journalist and editor. She discussed the importance of preparing lay materials for journalists and strategies for communicating results to the press. 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. The series is open to network operation centers and site staff.
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.	Ongoing.	Followed-up on "2011 DAIDS HIV/AIDS Clinical Trials Networks' Communications Symposium" priorities. 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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 is working with DAIDS to update the "SDMC Contact List".

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 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.	Completed evaluating research gaps and are currently developing specific research items/concerns to be completed in Q3.	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. The group selected a new chair after the previous chair stepped down.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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	<p>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.</p> <p>Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups.</p> <p>Partner with groups to incorporate a human rights perspective into capacity building and research participation.</p> <p>Create simple training materials from existing content describing Community Partners as well as the science and structure of the networks.</p> <p>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"</p>	<p>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.</p>	Ongoing.	<p>In partnership with DAIDS, the group developed two eLearning modules based on the CP Training Materials that are currently available on the DAIDS LMS. 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.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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	<p>Develop a continuous quality improvement process for CP.</p> <p>Developed and administered Site CAB and Site Staff Surveys to assess community participation at the site level.</p> <p>Identify objective metrics and mechanisms for evaluating the impact of CP activities.</p>	<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.	<p>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 was due October 2011. About 100 CABs and site community coordinators responded. Analysis is underway. The group is currently developing a draft survey for the purpose of evaluating the impact of CP activities.</p>
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	<p>Research current site/CAB funding structure to understand the system.</p> <p>Develop the CP Site CAB and Site Staff Surveys to assess community participation at the site level.</p> <p>Partner with the network leadership to assess how the site funding mechanism has impacted community involvement at the network, CTU and CRS level.</p> <p>Identify expectations for CAB support and funding that tie into cross-network community evaluation and make actionable recommendations to network leaders and DAIDS.</p>	<p>Adequate site-level CAB support.</p> <p>Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites</p>	Ongoing.	<p>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. Favorable reviews were received and the revisions resubmitted. The group assisted with the revised the 2011 CP Site CAB Survey.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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. Nominated a new NLOG/SWG rep to replace the NLOG/SWG rep that stepped down. Discussed the focus and agenda for a 2012 CP F2F Meeting. In the process of drafting an abstract for participation in the IAS 2012 Global Village.
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: Informed Consent Process; Management of Pregnancy and Contraception on Study, and; 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. Invited Judy Brooks and Linda Ehler from DAIDS to join the working group for the purpose of working together to provide input and update the DAIDS IC documents/process. Queried sites to collect tools/documents used to assess the informed consent process.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 focusing on the CP training materials was featured during the 2011 Unity Through Diversity Conference in October 2011 in Albany, NY. An overview of the 2010 CP Site CAB and Site Staff survey was presented at the 2011 USCA Conference in Chicago in November. 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. Increased internal collaboration with other HANC coordination areas to enhance the overall mission of Community Partners.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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. 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. 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, network leadership, and site staff. The survey outcomes have informed the updating of the Best Practices document. The document may inform the site FOA and will be finalized in Q3.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 January 2012. 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 and up-versioned to the current MedDRA standard. SDAC coders are running beta tests with mappings and HANC has coordinated ad hoc reviews with DAIDS-affiliated clinicians. SDAC programmers will demo the tool internally in January 2012, incorporate feedback, and make available to investigators in Q3. HANC will help circulate notice of the tool and host a series of "brown bag" webinars for interested researchers. The WG will pursue hosting similar sessions at upcoming ACTG/IMPAACT meetings.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 and safety reporting. The DMCs discussed developing a consensus statement addressing DMC data harmonization concerns. DMC members have participated in discussion to harmonize behavioral elements in network studies. Drafted and shared the "MedDRA Implementation Working Group Charter" for DAIDS/RSC review. FSTRF presented on the recently finalized "Appendix 100" which merged ACTG and IMPAACT clinical code appendices 40, 50 and 60. Discussed ways to improve the DAIDS-ES format and communications with product champions. HANC invited the DAIDS-ES Business Manager to attend an upcoming call.
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.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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. 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. HANC convened the statistical PIs of the networks and OPCRO to discuss new FDA rules addressing the unblinding of adverse events data. The conversations led to a new procedure adopted by DAIDS and the networks.
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 All Collaborators 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 hosting a F2F meeting when CROI meets in Seattle in March 2012 or 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 Q2
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 are 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.	Concept Systems Inc. (CSI) and HANC have been working with the ad hoc WG to develop a survey to understand the functioning of the 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. Discussion also continues on how to determine the structure for communications and how the survey should be disseminated. The Site Coordinators WG is currently Beta testing the survey.
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.	HANC is collecting from the Networks all publications from 2009-2010 and data cleaning will begin for the next bibliometric analysis.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 CP Site CAB Survey was closed in October and data analysis is underway. During a cross-network evaluation call, it was asked of each network's evaluation chair whether or not there would be interest in collaborating on one CAB survey for all of the networks to use in order to streamline the survey. This item is under discussion within each of the networks.

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.				
ACTG/IMPAACT LTC and HANC Support Staff	Maintain a Lab Tech (LT) Committee Workload Tracking System; generate reports as requested.	Track information about LT work assignments to ensure equitable sharing of responsibilities and accurate awarding of credit.	Maintain and update data throughout the year; Q3 further develop reporting system.	Updated the LT Workload Tracking System with current protocol and lab tech information in an ongoing manner.
Lab PI/Manager Committee	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion and updates from the laboratory working groups.	Ongoing.	Distributed 2 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	Held 4 calls during which the group: Shared information about upcoming site visits; Collaborated with SMILE and DCLOT to resolve an issue with hCG testing; Provided guidance for the re-publication of the Cross-Network PBMC Processing SOP; Reviewed and redefined the role of the Primary Network Lab (PNL) and use of the PTPT System; Determined that posting of lab certificates to the HANC Lab Certificate Library would be mandatory for only some networks; Determined that lab import permits would not be

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
				posted publicly; Drafted a request to DCLOT regarding the standardization of DAIDS lab visits; and Drafted a survey for labs using the Abbott m2000
HANC Support Staff	Maintained and updated Laboratory Coordination and Laboratory Resources portions of the HANC public website.	Provide clear information to the general public and laboratories about the working groups and their roles and make various resources available to labs.	Ongoing.	Regularly updated page about ordering fetal bovine serum; Regularly updated VQAAB reports and minutes; Regularly updated VQA Laboratory Status and Laboratory Contact lists; and Added information about the Malaria Lab Network
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 2 calls during which the group reviewed updates to the performance summary
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.	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 Q2 while the IQA collects and tests additional samples.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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	FSTRF worked with pilot testing labs and the ICAG to develop reporting system.
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 Q2
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	Q2 Outline information that would be needed to make this determination and begin collection of information.	Outlined information needed; Began information collection; Collected PBMCs thawing/resting SOPs from processing labs, testing labs, networks, IQA and began comparison document; and Received presentation of HVTN PBMC Quality Program
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.	Held 2 calls during which the group: Received updates from the CPQA and the networks; Discussed which TB and HCV drugs to add to proficiency testing panels; Approved the use of three runs for validation; Reviewed a comparison of operational imprecision; and Reviewed a new database being develop by the CPQA and FSTRF of primary specimen requirements for each assay
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.	Held 1 call during which the group: Received updates from the CPQA; Provided feedback on the online AVR/SOP submission utility; Reviewed PSL assay information; Discussed the best practice for long-term stability testing; and Discussed how many samples should be assayed when doing incurred samples.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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.	Held 1 call during which the group discussed various countries' policies for the export of biological samples and needs to develop in-country pharmacology testing capacity.
Virology Quality Assurance Advisory Board (VQAAB)	Maintain a structure, processes and a forum for consistent communication about and performance review of VQA labs. Review data and revise policies of the VQA PT program as necessary.	Consistent quality control of virology testing at network-affiliated laboratories.	Ongoing.	Held 3 calls during which the group: Reviewed PT reports and cumulative performance summaries; Reviewed the status of point-of-care technologies; Reviewed the status of testing for NWCS327; Approved the VQA's proposal for an HIV DNA dried blood spot proficiency testing program; Reviewed a report on the analysis of experimental genotyping samples, and; Approved a proposal for the modification of scoring for genotyping proficiency testing.
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; Ongoing: Update standard wording content.	Completed application of new formatting to standard wording templates. Updated standard wording content in 8 out of 10 sections.
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	Q2 Review and revise overall structure of Lab Manual; 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.	Reviewed and revised overall structure of Lab Manual.
PBMC SOP WG	Develop, finalize, translate and post version 3 of the Cross-Network PBMC Processing SOP.	Standardize PBMC cryopreservation across the networks to ensure access to high-quality specimens for use in network studies.	Q2 Update SOP to reflect changed IMPAACT policy for shipping of samples; request translations.	Published and posted v4.0 of SOP and requested translations with support of the CRSS contract.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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, and monitor work flows.	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.	Held 2 calls to: Reviewed a South African EQA program for the GeneXpert for possible use by ACTG and IMPAACT; Finalized the verification plan for Microbank tubes; Discussed the ACTG/IMPAACT SOP for clinic safety and; Reviewed site visit reports for 5 labs in Africa.
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.	Placed on hold in Q2.
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	Develop plan for group activities.	Prioritize the group's objectives and provide guidance for future calls and activities.	Q2 Survey group members for group priorities; analyze and review results; develop plan.	This project was completed in Q2.
Malaria Laboratory Network and HANC Support Staff	Develop resources library on MLN team site.	Provide a location and structure for the collection and organization of MLN resources, such as SOPs and guidelines documents, for group review and recommendations.	Q2 Develop and populate resources library; Q3 Use resources library to inform development of guidelines for the use of diagnostics in clinical trials.	Developed and populated resources library.
Malaria Laboratory Network and HANC Support Staff	Develop outreach materials.	Reach out to non-network organizations with similar goals to avoid duplication of effort and to maximize the expertise available within the group.	Q2 Develop MLN information flyer and HANC public website content; Q3 Develop poster; Ongoing – update as necessary.	Version 1 of the flyer was completed, posted on the HANC public website, and distributed at an international tropical diseases meeting.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Malaria Lab Network	Apply for funding for the development of standards and calibrators.	Develop a centralized resource for standards and calibrators for use in clinical trials with malaria diagnosis endpoints and the ability to reliably compare results across studies.	Q2 Collect and review funding opportunities; Q3 Write letter of interest and assess feasibility.	Reviewed funding opportunities and developed plan for moving forward.

Legacy Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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	<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.	<p>The Legacy Project has initiated engagement with five city and three state health departments, and established formal relationships with 13 CBOs and ASOs (Black AIDS Institute, National AIDS Education Services for Minorities, MOCHA, Black Gay Research Group, National Gay Men’s Advocacy Coalition, the Tacoma Art Museum, African American Young Men Who Have Sex with Men Working Group, South Carolina HIV/AIDS Council, Latino Commission on AIDS, Reach LA, COLOURS, NNAAPC, FHI360); collaborations with MTN and HPTN have been solidified. Legacy Project has initiated partnerships with the Adolescent Medicine Trials Network (ATN) and the CDC. Legacy developed a pilot project with Lincoln University as lead that will include nine other historical Black colleges. Legacy Project, in collaboration with the Latino Commission on AIDS, conducted two community consultations with Latino clergy and House/Ball communities in NYC. Legacy Project is collaborating with Emory University on the development of joint programming; Legacy established four new subcommittees of the Legacy Project Working Group (LPWG) in Q2, including: Membership (met two times); Research and Evaluation (first meeting scheduled on December 19, 2011); Engagement and Collaboration (met two times); Capacity Building and Technical Assistance (met two times); The Women’s HIV Research Collaborative (WHRC) and LPWG face-to-face meetings will be held in Washington, DC, on March 19 - 22, 2012; and Legacy Project will convene three additional face-to-face meetings in Q3 and Q4, including Creating Awareness Through Art (CATA), CBA/Indigenous Organizations, and House/Ball Leadership.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 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>	Increase scientific literacy and access to accurate and relevant scientific information among sites, governmental agencies, CBOs/ASOs, community groups and key leaders.	Ongoing.	<p>A concept proposal for a study on differential representation across networks was submitted to the Network Leadership Group, ACTG and HVTN in Q2, and we are currently reviewing and revising the proposal. The following abstracts were submitted:</p> <p><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: (submitted to LGBT Health Summit (accepted); 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>Development of the speaker's bureau as well as speaker roles and responsibilities is in progress.</p> <p>The National Native American AIDS Prevention Center (NNAAPC) - Legacy collaborative Native Americans Engagement in HIV Clinical Research (NAEHCR) Project was funded in November 2011 and project planning and development initiated.</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 awareness and recruitment of diverse MSM populations will be submitted in collaboration with the HVTN Social Scientists in January 2012. A third proposal, <i>Voices and Soul Tapestry Project</i>, collaboration between Legacy and Emory University, has been developed and will be submitted in Q3.</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, and will work with the Legacy Project Social Scientist to develop a research project that examines differences of risk perception among women of color.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 B 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 hosted a webinar on PrEP and implications for women in emerging HIV-related clinical trials; a second webinar is scheduled for January 24, 2012 and will be a follow-up to the 2nd International Workshop on Women and HIV.</p> <p>The Legacy Project hosted seven workshops/presentations in Q2, including:</p> <p>A plenary and two workshops at Unity Through Diversity Conference in October 2011, and;</p> <p>A plenary, a workshop and a roundtable at USCA in November 2011.</p>
Objective #4: Enhance the internal and external operations of the Legacy Project.				
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	<p>Individual professional development plans were developed in tandem with annual performance reviews in Q2.</p> <p>Logo redesign is in process; rebranding strategies are in development.</p> <p>The Legacy Project Strategic plan was finalized in Q2.</p> <p>Development for the communication plan will begin in Q3, to be finalized in Q4.</p>

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #5: Legacy Project in partnership with FHI360 will plan and implement the <i>Be the Generation Bridge</i> Partnership (BTG Bridge) project.				
Legacy Project Staff	<p>In partnership with FHI360, Legacy will establish a project management plan and administrative systems</p> <p>Legacy Project will hire a Project Manager, Program Assistant III and Community Engagement Officer to support the project</p> <p>Conduct formative research and develop process indicators</p> <p>In partnership with FHI360, develop RFA and Select Partners</p> <p>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>Increases awareness of the NIAID HIV/AIDS Clinical Trials</p> <p>Networks ongoing research in biomedical prevention of HIV in communities most at risk in the U.S.</p> <p>working with local, regional and national CBOS partnered with local HIV prevention clinical research sites.</p>	<p>September 2011- May 2012</p>	<p>The BTG Bridge Project team held a kick-off planning meeting September 27-28, 2011 in Washington DC. Legacy Project and FHI 360 met along with NIAID and NOVA representation; Developed a FHI360 and Legacy Project team planning meeting schedule and communication matrix. Submitted a BTG Bridge management plan to NIAID. Four working groups were established with representation from FHI360, Legacy Project, NIAID, MTN, HVTN, and (Research/Evaluation, Messaging/Materials, Partnerships, and Conferences and Meetings).</p> <p>Legacy Project hired Denee McCloud, Project Manager, Anjali Desai, Program Assistant III, and Bertram Johnson, Community Engagement Manager.</p> <p>Literature review was conducted. Stakeholder interview script was developed. Stakeholder interviewers were selected; Stakeholders interviews began in November and will be completed in December. Process indicators for project components were developed and sent to NOVA for review.</p> <p>The RFA was developed and released on October 2011 with a November 9th submission deadline; thirty-six applications were received; reviewers were identified and confirmed; a review process was scheduled for December 2011.</p> <p>An organizational assessment was designed and scheduled to be distributed to partners in December 2011; a date and venue for the partner training was finalized; a draft agenda for the training was developed; a conference strategy was developed and staff leads were selected for most meetings; BTG Bridge purchased an ad for the Unity 2011 conference in October and hosted an exhibitor booth at USCA 2011 in November.</p>

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 October 2011 NLOG call focused on the HANC Behavioral Sciences Work Group reports for the annual meeting in May and the two focus group meetings in April.

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.

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. HANC and DAIDS leadership also hold monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC also holds a monthly call with the leadership of OCSO and a bimonthly call with OPCRO leadership. HANC facilitated three network leadership Group calls in Q2, and two calls with DAIDS 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 also considered the feasibility of harmonizing the approach to following seroconverters across networks and developed recommendations for the Network Leader's Group. One WG call occurred in Q@ and the final report of the WG was presented to the Network Leadership Group on their November 2011 call. A manuscript of the report's findings and recommendations is being drafted for consideration of publication.

Site Management & Logistics Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 has been reviewing new HHS rules and monitoring Federal guidance and related assessments. Updates to the SOP and web development will commence in Q3.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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 two calls with OPCRO and three calls with OCSO. OCSO has indicated interest in providing input on the development of the pluripotent site survey (see evaluation objective #2). OPCO has indicated that they will work with the RSC to provide sites with highlighted changes when revised FDA package labels are sent to the sites by RSC.
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 joined a call to participate in these discussions. The DAIDS ON TRAC WG received feedback on DAIDS Training resources flier. The WG also provided input on the pluripotent survey (see evaluation objective #2), suggested PR Manual changes sent to the PRO, sent informed consent documents and tools to be shared with the CP Ethics WG (see community objective #6) and viewed several new DAIDS eLearning modules in the DAIDS LMS.
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 Q2
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 were viewed with the Committee in the DAIDS LMS. The training announcement communication plan has been revised to have OCSO send one announcement to all CTU and CRS PIS and site coordinators. Once the announcement has been sent, Christie sends the message to all training representatives and the HANC network operations alias list to inform all of the notice in order to have consistent messaging to the sites. Each network training rep also shared relevant plans for their upcoming network meetings.
Objective #2: See Community Coordination Objective #2.				