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Infrastructure and Administrative Support

The HANC Public Website

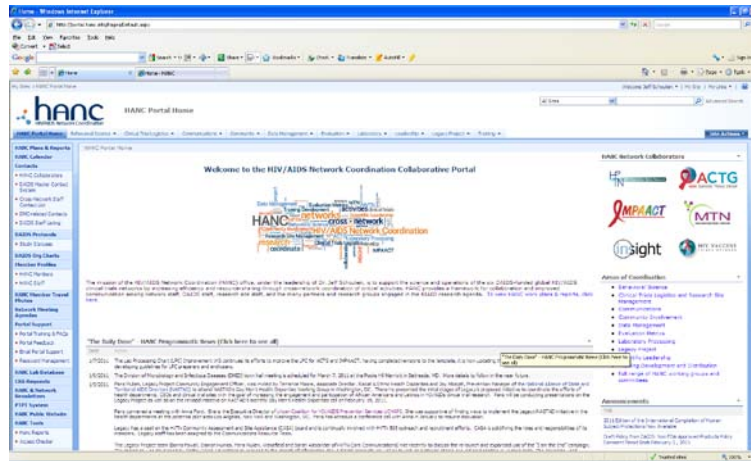
The HANC public website (www.hanc.info) provides information and resources for collaborators, research sites, and the general public. HANC released its newly branded site early in June 2010. Functionality and content added to the website this quarter included:

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



| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|-----------------|---|---|----------|--|
| HANC & IT staff | Public site updates and rebranding project. | Improved capacity, ease of navigation flow and access to information. | Ongoing. | Launched new site and HANC is in process of implementing phase II design plans. HANC staff has been uploading images and documents and created a BSIG Publications Library . |

The HANC Portal



The HANC Portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. During this quarter we had a net gain of 37 individuals with HANC portal user accounts, for a total of 980 active HANC Portal user accounts. Three additional team sites were developed this quarter, including the MTN Behavioral Science Research Group document library, the FHCRC Legacy team site, and the Community Partners Writing Team for a total of 61 team sites. HANC portal projects for 2010-2011 include:

| 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 has been installed on the HANC public web site and the portal. HANC staff reviews usage reports on an ongoing basis. |
| HANC staff | Provision of the DAIDS-ES protocol reports on the HANC portal. | Ready access to all protocol reports including the quick summary data and accrual data from the DAIDS-ES system in real-time for HANC portal users. | Development completed. | Ongoing activities include embedding links to protocol reports in call minutes, linking to protocols referenced in the HANC newsletter, and updating the protocol report details as necessary. |
| HANC staff | Feasibility of linking all approved network protocols on the HANC portal to the DAIDS-ES document library. | Ready access to all network approved protocol documents for HANC portal users. | 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. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|------------|---|---|----------|--|
| HANC staff | Adding features and resources for HANC members. | Improved resource and information sharing amongst HANC members. | Ongoing. | Expanded the member profile library, and reorganized the portal homepage and navigation. |
| HANC staff | Upgrade to SharePoint 2010 | Improved functionality and ease of use. | Ongoing. | Consulted with IT staff to determine feasibility and timeline. |

Social Networking & Information Sharing

HANC has established Twitter (search for “Hancprograms”) and Facebook (search for “Hanc Programs”) accounts to share general programmatic updates with a broader audience. Due to the interest in the resources shared in the HANC newsletter, HANC staff has increased the publication frequency from bi-monthly to monthly. “HANC Portal 101s” are now offered on a monthly basis and “as requested” basis. HANC members are invited by HANC to participate in a walk-through of portal/website resources. HANC staff inaugurated monthly SharePoint trainings in Q2. The sessions focus on the collaborative features of SharePoint technology.

Behavioral Science Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|--|---|----------|--|
| Objective #1: Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science. | | | | |
| Behavioral Science Working Group | Propose behavioral science plenary sessions to network conference planning committees. Curate and organize sessions. | Identify network and behavioral science agendas/priorities and identify gaps, overlaps and provide input from the behavioral science perspective in shaping agenda items. | Ongoing. | The BSWG will continue to propose topics for network meetings. The group discussed the possibility of hosting symposia at the Spring 2011 HPTN/IMPAACT and ACTG conferences. Upon request, HANC created a repository for the MTN Behavioral Science Research Group meeting documents on the HANC portal. |
| Objective #2: Create a repository of behavioral science tools and measures. | | | | |
| Behavioral Science Working Group, NIMH | Create a library on the HANC portal for all BSIG members to access “state of the science” measures, forms, and articles. | Allow investigators to compare efficacy of research tools and share outcomes of behavioral science substudies/practices in network clinical trials. | Ongoing. | The portal library has been created and is updated on an as needed basis. To date, over 247 documents have been loaded to the site. A Behavioral Social Science library with links to PubMed abstracts has been created on the HANC public website. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|--|---|----------|---|
| 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 and Adherence Measures” table is updated on an as needed basis. The BSWG has reviewed network CRFs and BSS elements calls/webinars. |
| Objective #4: Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings and workshops. | | | | |
| Behavioral Science Working Group, NIMH | Provide opportunity for investigators to share ideas and collaborate on behavioral science materials and recommendations. | Ensure that the best quality behavioral science is integrated into clinical trials. | Ongoing. | The Working Group discussed ongoing network behavioral and social science activities and deliberated on focus group topics. USAID’s Margaret McCluskey consulted BSWG members on potential authors for a Risk Assessment Best Practices article proposal. |
| Objective #5: Study and promote the development and implementation cross-network/trans-Institute studies and/or behavioral data elements in network studies. Analyze funding and review procedures. | | | | |
| Behavioral Science Working Group | Identify areas of opportunity and challenges in the development/implementation of cross-network/trans-Institute protocols. | Ensure that the best quality behavioral science is integrated into clinical trials; reduce redundancy. | Ongoing. | Discussed goals on monthly conference calls. Shared objectives at HANC’s October 2010 SWG presentation. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|--|----------|---|
| Objective #6: Improve information exchange among network-affiliated behavioral and social scientists. | | | | |
| Behavioral Science Working Group, Behavioral Science Interest Group | Compile a list of network-affiliated behavioral and social scientists and create a “Behavioral Science Interest Group” (BSIG) distribution list modeled on the NLOG. The list allows investigators to share updates in the field, innovative research methods, and links to seminal papers. | Improved communication and circulation of ideas. | Ongoing. | Created BSIG listserv, portal-based resource center, and publications library on the public website. HANC circulates a weekly digest of newly published BSS articles, CRFs, funding opportunities, job openings, blog posts, etc. Over 200 behavioral and social scientists have joined the Behavioral Science Interest Group since its inception at the beginning of Y5Q1. Richard Lester presented on his study which found that text messaging can improve ART adherence . |

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. | HANC hosted a joint call with Network Leaders and the Communications WG to discuss the iPrEx results and implications for DAIDS network trials. HANC created a webpage to highlight network responses to the study, links to network PrEP trials, and created a network press release library. NIAID confirmed it would link out from press releases to the network websites. HANC staff attended and presented at the AVAC PrEP and Vaccine Communications WG meetings. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|--|-------------------------------|--|
| Objective #2: Consider ways to harmonize network communications strategies and external relations policies. | | | | |
| Communications Working Group | Areas of interest include: review and identify points of commonality across network websites; discuss network policies regarding posting protocol documents on public websites; network website recruitment strategies; links to outside parties including all other networks; evaluate 508 compliance on network websites. | Harmonize network communications activities and to reinforce the interconnectedness of all areas of DAIDS-funded clinical trial research. | Ongoing. | HANC paired networks and DMCs to review network sites with the goal of identifying possible areas of harmonization and considering how each network maximizes its web presence. Ongoing discussion of network policies around posting protocols or synopses. NIAID confirmed it would link out from press releases to the network websites. Discussed 508 compliance and circulated NIAID guidance. HANC hosted a joint call with Network Leaders and the Communications WG to discuss the iPrEx results and implications for DAIDS network trials. HANC created a webpage to highlight network responses to the study, links to network PrEP trials, and created a network press release library. |
| Objective #3: Develop a Communications Resource Center (CRC) on the HANC portal. | | | | |
| HANC Staff | Create a portal-based library of communications resources including: articles, guides, presentations, contact information, Best Practices, and white papers. | Facilitate communication and share Best Practices across the networks and provide opportunity for clinical trials communications professionals to develop relationships. | CRC created. Updates ongoing. | The CRC is a library of communications resources including: articles, guides, presentations, contact information, best practices, and white papers. Network communications staff and professionals in the field have access to the site and are encouraged to contribute content. HANC staff demonstrated the CRC at the AVAC Communications WG meetings. Non-network partners include representatives from MMCI, AVAC, and IAVI. HANC is exploring expanding the CRC membership to a broad array of HIV/AIDS advocates and research organizations. HANC began creating a media contact list for CRC members. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|--|---|----------|---|
| Objective #4: Share IT- and communications-related developments across all areas of coordination. | | | | |
| HANC Staff | Standing opportunity to share programmatic updates on conference calls across all areas of coordination. Examples include: the IT Best Practices document developed by the DMC Harmonization Working Group; Community Partners and the Site Coordinators Working Group concerns about IT needs at resource-limited sites; implementation and use of DAIDS-ES web services; privacy and IT security issues; Legacy Project activities in the field and use of social media. | Improved communication across networks and HANC activities. | Ongoing. | Cross-cutting issues are addressed on HANC calls and outcomes are shared via email. Programmatic updates are posted on the Daily Dose, Twitter, Facebook, and in the HANC newsletter. Guests are invited to join working group calls on an ad hoc basis. Q2 calls addressed HANC and network website redesign projects, strategies to encourage use of collaborative websites, and the value of protocol-specific websites. WG members discussed the cross-network trend towards making more documents available on the public websites as well as tips/considerations for networks as they advance through the redesign process. WG members worked with AIDS.gov to reorganize and highlight the series of DAIDS network restructuring blogs . The DMCWG continues to discuss use of intra-DMC project management software and HANC updates other relevant WGs as necessary. |

| 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. Katharine Kripke (NIAID) and Caroline McLeod discussed NHVREI's evaluation efforts. Pursued development and launch of the AIDS.gov Google map widget: the real-time map of DAIDS clinical trial sites will be displayed on hanc.info, on participating network websites, and on the AIDS.gov service locator. The group began discussing strategies to encourage use of collaborative websites and the value of protocol-specific websites. Q3 calls will be dedicated to the development of evaluation metrics and community engagement practices. |
| Objective #6: Review and make recommendations about communications best practices and evaluate available resources such as the Microbicide Media and Communications Initiative "Clinical Trial Handbook". | | | | |
| Communications Working Group | Review and recommend network communications Best Practices. | Harmonize network communications activities and to reinforce the interconnectedness of all areas of DAIDS-funded clinical trial research. | Ongoing. | IAVI communications staff presented on their social media protocol audit and outcomes. Q3 will be dedicated to distilling best practices and lessons learned from RV144, CAPRISA 004, and iPrEx communications campaigns. |
| Objective #7: Invite key stakeholders, opinion-makers, and experts in the field to present on Working Group calls. Areas of expertise could include: journalism, advocacy, blogging, and cultural anthropology. | | | | |
| Communications Working Group, IT Infrastructure Working Group | Engage communications professionals on monthly conference calls and ad hoc webinars. | Deepen understanding of new tools; learn from other organizations experiences and expertise; share ideas across an array of domains; provide opportunity for clinical trials communications professionals to develop relationships. | Ongoing. | Q2 presenters included: Michelle Samplin-Salgado (AIDS.gov), Soyon Im (Internet Strategies Manager, HVTN), Katharine Kripke and Caroline McLeod (NHVREI and Nova Research), Leetha Filderman (PopTech and Project Masiluleke). |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|--|----------|--|
| Objective #8: Identify, implement, and maintain tools to improve cross-network communication. | | | | |
| HANC staff | Maintain resources such as the DAIDS staff listing, data management related contact list, cross-network collaborator list, network newsletter library, archive of network meeting agendas, disseminate DAIDS and network updates. | Foster communication and access to contacts within the DAIDS and network structures. | Ongoing. | Updated libraries and resources as able; solicited articles from the networks for inclusion in monthly newsletters; posted updates and notices to the HANC portal's Daily Dose, Twitter feed, and Facebook page. Standing opportunity to share programmatic updates on conference calls across all areas of coordination. Discussed partnering with AVAC to create a protocol timetable for HIV/AIDS clinical trials. Launched the HANC blog and invited networks to submit posts. |

Community Coordination Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in 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. | Identify network and community scientific agendas/priorities and identify gaps, overlaps and provide input from the community perspective into the research agenda. | Completed prioritization, disseminated results and are currently evaluating research gaps. | The group presented the ranked list to full CP and presented the results to DAIDS and Network Leadership at the October 2010 SWG Meeting. The group invited community advocates to review and provide feedback on the HIV research priorities through the HANC blog. Upon request from DAIDS the group was charged with identifying which research areas listed on the CP Research Priorities are not currently being addressed in ongoing or protocols in development. |

| 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 develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules. | | | | |
| Community Training Working Group | <ul style="list-style-type: none"> Utilize the Community Training Working Group to share existing CAB training materials; identify and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules. Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups. Partner with groups to incorporate a human rights perspective into capacity building and research participation. Create simple training materials from existing content describing Community Partners as well as the science and structure of the networks. | Common CAB member understanding of basic concepts in HIV disease, clinical trials methodology, and CAB role. Improved training quality and consistency. | Ongoing. | In partnership with DAIDS, this group worked on an evaluation tool to determine the effectiveness of the train the trainer sessions of the newly developed curriculum at the DAIDS Regional Training Events in Pune, India in May 2010 and Lusaka, Zambia in August 2010 and the upcoming training in Durban, South Africa in May 2011, to train the site staff and offer the course at their sites for their community members and new site staff. Developed a strategy to promote CP training materials at Network meetings and at CTU level. Initiated discussions on developing integrated infectious disease training for all staff working with CABs, which will include CP Recommendations Document. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|--|--|----------|--|
| Objective #3: Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact and serve as an advisory group to the EMTF. | | | | |
| Community Partners Evaluation Working Group | <ul style="list-style-type: none"> • Develop a continuous quality improvement process for CP. • Developed and administered Site CAB and Site Staff Surveys to assess community participation at the site level. • Identify objective metrics and mechanisms for evaluating the impact of CP activities. | <p>Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.</p> <p>Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites</p> | Ongoing. | In collaboration with the EMTF and CP site-level funding WG distributed the executive summary of the CP survey results and formed a writing group to draft and publish the results of the CP survey. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|--|----------|--|
| 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 CP site-level funding WG distributed the executive summary of the CP survey results and formed a writing group to draft and publish the results of the CP survey. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|---|----------|--|
| Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming network recompetition and restructuring process. | | | | |
| Community Partners | Solicit input from networks and other interested groups to provide input and recommendations to DAIDS regarding the Network recompetition and restructuring process. | Identify network and community concerns and provide input in shaping the DAIDS recompetition and restructuring process. | Ongoing. | Tasked the Executive Committee with gathering and facilitating feedback and input to DAIDS on the upcoming and recompetition and restructuring process. Developed talking points for ARAC, SWG and NIAID Town Hall Meetings. Initiated contact with other infectious disease groups regarding their community engagement structure and if they would like to participate in providing input into the upcoming network recompetition and restructuring process. |
| Objective #6: Review the following topics across the networks, identify areas where there are problems or opportunities for improvement and work in collaboration with Network Leadership and DAIDS to address these issues. | | | | |
| Community Partners Ethics Working Group | Solicit input from networks and other groups to provide input and recommendations to DAIDS and Network Leadership regarding: <ul style="list-style-type: none"> • Informed Consent Process • Management of Pregnancy and Contraception on Study • Trial design relative to guidelines/local standard of care • Placebo arms in prevention trials | Identify areas where there are problems or opportunities for improvement to address these issues. | Ongoing | Held conference calls and began focusing on management of pregnancy and contraception while on study, which will include collaboration with the HANC Women's Research Collaborative. Continuing work with OPCRO to review and address the scientific, clinical, ethical, community and personal issues at stake in dealing with contraception and pregnancy in the context of clinical research participation. |

Data Management Center Coordination Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|--|------------------------------|---|
| Objective #1: Implement Information Technology Best Practice Standards developed in Year 3 at DAIDS clinical trials study sites/affiliated laboratories and monitor infrastructure changes. | | | | |
| DMC Harmonization Working Group | Implement Information Technology Best Practice Standards developed in Year 3 at DAIDS Clinical Trials study sites and affiliated laboratories. Monitor infrastructure changes. | Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems. | Review and updating ongoing. | Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. Created IT Best Practices Document Taskforce to review the documents, make recommendations, and consider possible application of IT Best Practices at DAIDS-funded sites. The Taskforce includes representatives from the DMCs, OCICB, and DAIDS. The group is developing a survey to be sent to sites. |
| Objective #2: Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization. | | | | |
| DMC Harmonization Working Group | Maintain code mappings across LIMS systems and modify specimen inventory data elements as requested by SCHARP to track and QA data. Work with individual collaborating partners to ensure that previously identified common data elements are included and supported in electronic manifest files readable across multiple systems and reported back to SCHARP in an inventory data feed. | Electronic manifest files readable across multiple systems and reported back to SCHARP as part of an inventory data feed. | Ongoing. | Discussions with DAIDS are ongoing. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|---|-----------------------------------|--|
| 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. Invited DAIDS staff to join calls and discuss training needs resulting from the EAE Manual revisions. |
| Objective #4: Harmonize MedDRA coding. | | | | |
| AIDS Defining Events Working Group | Reconcile CDC and WHO diagnostic classifications with MedDRA codes | Realize DAIDS' mandate to use MedDRA codes in DAIDS-funded clinical trials | Ongoing. Expect resolution in Q3. | Mappings have been completed and up-versioned to the current MedDRA standard. SDAC coders are running beta tests with mappings and HANC staff has coordinated weekly reviews with DAIDS-affiliated clinicians. |
| Objective #5: Harmonize data definitions and standards for compatible all-network use. | | | | |
| DMC Harmonization Working Group | Identify data elements to be harmonized across network studies. | Improve efficiency and harmonization. Allow for cross-network studies/analyses. | On hold. | DMCs are considering higher priority areas for harmonization and provided suggestions to DAIDS. Project formally on hold pending DAIDS' recommendations. The WG continues to discuss use of intra-DMC project management software. |
| Objective #6: Implement clinicaltrials.gov results reporting requirements. | | | | |
| DMC Harmonization Working Group | Network Leaders asked that HANC work with DMCs to address cross-network issues and points of ambiguity. | Improved communication. | Ongoing. | Opportunity to share updates on monthly calls. HANC reports on Site Coordinators WG and Network Leader comments as appropriate. |

| 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 is working with DAIDS to create a "Protocol Reporting List" to help networks and sites identify protocol-specific EAE Manual reporting requirements. HANC disseminated DAIDS-issued memos. |
| Objective #8: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS). | | | | |
| DMC Harmonization Working Group | Provide DMC perspective and feedback to DAERS program staff and DAIDS leadership. | Ensure DMC systems are considered in the development and implementation of policies relating to DAERS. | Ongoing. | Opportunity to discuss experiences using DAERS on monthly and ad hoc conference calls. HANC invited DAERS product champion to join a call and discuss the process for QC and RSC's role in reviewing the data. |
| Objective #9: Coordinate a one day DMC face-to-face meeting. | | | | |
| DMC Harmonization Working Group | DMC representatives will use the time to present ongoing intra-DMC projects and consider additional areas of coordination. | Improve efficiency and harmonization. | On hold. | On hold pending further discussion and identification of agenda items. A F2F meeting will possibly be held in mid-2011. |
| Objective #10: Create an email alias for DMCs and network operation center staff. The list serve will be a vehicle to share important DAIDS updates and HANC working group activities. | | | | |
| HANC Staff | Create a DMC/network operations center staff alias. | Improved communication across DMC and network operation staff. | Q1. | Completed. The alias is used for relevant DAIDS' memos and policies and cross-cutting updates. |

Evaluation Coordination Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|--|----------|---|
| Objective #1: Work with CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes. | | | | |
| Evaluation Measurement Task Force | Hold calls as needed with each working group and CSI to advance the development of an evaluation system. | Develop evaluation metrics and processes to evaluate DAIDS and network success and identify opportunities for improvement. | Ongoing. | <p>Calls with the EMTF planning group are ongoing every month.</p> <p>HANC and Community Partners shared the final survey report based on the online survey, which was conducted from April-May 2010. The survey collected feedback from the Site Community Advisory Boards (CABs) and Site Research Staff Community Coordinators at the DAIDS-supported HIV clinical research sites. This was the first cross-network survey conducted by CP. A writing group is drafting a manuscript. The protocol implementation timeline analysis is ongoing. A manuscript on the bibliometric analysis was submitted for publication in Q2 to PLoS ONE.</p> <p>Planning is ongoing for a study of pluripotent sites and community involvement at the network level.</p> |

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 | LT Workload Tracking System updated with current protocol and lab tech information in an ongoing manner. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---------------------------------------|---|--|---|---|
| Lab PI/Manager Committee | Maintain a structure and processes for consistent communication and access to critical information. | Provide a forum for cross-network discussion and updates from the laboratory working groups. | Ongoing throughout the year. | Distributed 2 sets of laboratory working group updates. |
| LFG-DCLOT Collaborative Working Group | Determine process for laboratory relocations. | Streamline communications necessary for laboratory relocations. | Q2 Develop, finalize and distribute process | Held 2 calls to develop a laboratory relocation process with representatives of OCSO and to clarify DCLOT's position on the validation requirements for rapid tests. |
| Lab Focus Group | Maintain a structure and processes for consistent communication and access to critical information. | Provide a forum for cross-network discussion and resolution of issues that affect multiple networks. | Ongoing | Held 6 calls during which the group: <ul style="list-style-type: none"> • Determined a cross-network approach to the validation of rapid tests • Formulated a plan to monitor the marking of critical items on laboratory action plans • Agreed to SMILE's recommendations for reporting EQA heme autodifferentials • Agreed to require the LDMS Storage Module for all specimens • Agreed to PBMC SOP WG's recommendations to require purchase of sterile reagents for PBMC processing, require use of a PBMC Processing Worksheet, and allow for the generation of laboratory SOPs • Agreed not to require the use of viable cell counts for cell calculations • Approved guidelines for development of back-plans • Discussed with members of DCLOT options for delivering laboratory training |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|---|--------------------------------|---|
| 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 |
| HANC Support Staff | Develop and maintain a HANC Laboratory Database for network-affiliated international labs. | Provide a common resource for the storage and maintenance of laboratory information; develop consensus laboratory names to ease communications among network laboratory staff and contractor staff. | Ongoing. | On hold during Q2 pending upgrade of the HANC portal to SharePoint 2010. |
| Objective #2: Ensure standard quality assurance for all of the protocol-specified assays conducted in DAIDS-sponsored network clinical trials across networks and other partners through the development and implementation of a Total Quality Management (TQM) Program. | | | | |
| Lab Focus Group/LFG-DCLLOT Coll. WG/IQA CD4 WG/VQAAB | Develop guidelines for back-up plans for safety testing, CD4 testing and virology testing labs. | Consistent quality control of safety, CD4 and virology testing at network-affiliated laboratories and back-up labs. | Q2 Finalize and post | Finalized and posted guidelines. |
| 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. | <p>Held 2 calls during which the group:</p> <ul style="list-style-type: none"> Discussed and resolved testing issues at labs Revised a draft flow cytometry instrument evaluation plan Discussed the results of an instrument comparison conducted by the IQA Discussed external quality assurance for CD19 |
| IQA Cryopreservation Proficiency Testing Advisory Group (ICAG) | Develop IQA intervention, corrective action, remediation and training approach; | Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories. | Completion target Q4 (May 11). | Requested an IQA study of Day 1 vs. Day 2 viable recovery counts |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|--|--|---|--|
| ICAG | Maintain a structure, processes and a forum for consistent communication about and performance review of IQA PBMC labs. | Consistent quality control of IQA PBMC cryopreservation testing at Network-affiliated laboratories. | Ongoing throughout the year. | Reviewed proficiency testing 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. | Q2 Review results of pilot study; Y5Q3-Y6Q2 Collect and analyze additional samples; Y6Q3 Evaluate results | Reviewed the results of a pilot study of PBMC samples stored at the Biomedical Research Institute and discussed next steps |
| 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 Finalize and post | In progress. |
| CPQA working groups (Advisory Board and Lab Group) | Maintain a structure, processes and a forum for consistent communication about the CPQA PT program and labs. | Consistent quality control of pharmacology testing at Network-affiliated laboratories. | Ongoing throughout the year. | Held 3 calls during which the CPQA working groups communicated program details to relevant parties and reviewed: <ul style="list-style-type: none"> • Updates to policies and procedures for AVR/SOP submission, validation of assays in rare matrices, and proficiency testing • Changes to the PK tutorial • Updates from the audit program • Additions of new labs to CPQA program • New members of the Advisory Board • A statistical analysis of the number of runs needed for assay validation • The formation of a new group to serve as a forum for the discussion of scientific questions that affect the pharmacology specialty laboratories. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|--|---|--|
| 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 proficiency testing program as necessary | Consistent quality control of virology testing at network-affiliated laboratories. | Ongoing throughout the year. | Held 3 monthly calls during which VQAAB: <ul style="list-style-type: none"> Reviewed proficiency testing reports and cumulative performance summaries Approved the use of external 200cp/mL controls Reviewed an HIV DNA validation plan developed by the VQA Discussed the possibility of forming an HIV DNA dried blood spot proficiency testing program Discussed the potential for initiating quality assurance for hepatitis and HPV 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. | Q2 Complete updates to standard wording and conduct reviews and initiate reformatting; Q3 Develop user guides and finalize standard wording in light of approved template | Continued revisions to standard wording. Initiated reformatting of LPC template |
| Lab Focus Group | Recommend and implement new real-time viral load assay for use in network protocols with viral load primary endpoints. | Ensure reliable and consistent data collection. | Q2 Complete installation, validation and training. | Held 2 calls with Abbott to review status of implementation and provide information and guidance; status of installation pending. |
| 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 Initiate revisions; Q3 Finalize and post; Q4 Translate | Held 4 calls to review suggested changes and further harmonize the SOP. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|---|--|--|---|
| Objective #4: Continue collaborating amongst the Networks, HANC, DAIDS and SMILE to improve TB diagnostics, TB proficiency testing and participation of labs with TB diagnostic capacity in Network protocols where TB is a component. | | | | |
| TB Diagnostics Working Group | Maintain a structure and processes for consistent communication and access to critical information. | Provide a forum for communication among the networks, SMILE and DAIDS regarding TB laboratories and diagnostics. | Ongoing. | Held two calls to discuss: <ul style="list-style-type: none"> • CDC SOPs and resources • Evaluation of the GeneXpert for urine, gastric aspirant, saliva and stored plasma samples • Laboratory structure and EQA for A5295 |
| TB Diagnostics Working Group | Develop draft language for network protocols that use TB diagnostics. | Provide standard language for networks to use in protocols that use TB diagnostics. | Placed on hold in Year 4. | This project is on hold. |
| Objective #5: Collaborate among the networks, HANC, DAIDS and SMILE to establish a Malaria Laboratory Working Group. | | | | |
| Malaria Laboratory Working Group | Determine working group membership, purpose and goals | Establish a forum for cross-network communication regarding malaria laboratories and diagnostics. | Q2 Establish membership and initiate discussions of working group purpose and goals; Q2-3 Share critical information across group members in order to finalize working group purpose and goals | Held 3 calls to: <ul style="list-style-type: none"> • Review the options for optimizing and standardizing microscopy • Review current network protocols/other group studies with malaria diagnostics endpoints • Review quality assurance of microscopy within the context of P1068s |

Legacy Project Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|---|----------|---|
| Objective #1: Continue the development of the HANC cross-network Legacy Project. | | | | |
| Legacy Project Leadership Team | Develop a HANC cross-network Legacy Project including detailing the project scope, intent, timeline and criteria to determine project success. | Enhanced cultural competency within the networks and build relationships of trust with African-American and Latino communities within the U.S. to enhance participation of African-Americans, Latinos, and Latinas in network trials. | Ongoing. | Continued search for Legacy Project Scientific Director and recruited a new Legacy Project Manager. Damon L. Humes, MHS, began working with the Legacy Project as a program consultant on October 3, 2010 and will assume a staff role on February 1, 2011. Continued ongoing coordination with the HVTN Legacy activities. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|------------------------------------|--|----------|---|
| Objective #2: Continue implementation of the Legacy Project transition strategy across the DAIDS-funded networks to ensure activities build upon and include HVTN-focused Legacy Project activities and the cross-network expanded activities. | | | | |
| Legacy Project Leadership Team | Continue with transition planning. | Ensure collaboration with the HVTN Legacy Project and the HANC cross-network Legacy Project. | Ongoing. | Regular meetings were held with the HVTN Community Relations and Education Unit, Legacy Project, Site Expansion Team, and Community Assessment & Site Assistance Group (CASA). Legacy Project staff participated to support HVTN and ensure increased opportunities for cross-network expansion and representation into the strategic plan. Legacy Project Community Engagement Officers substituted the term “HIV clinical research” in place of singular references to individual network research to allow for a cross-network approach and increased opportunity to support a wide range of prevention and therapeutic research studies. At a Legacy Community Luncheon during Nashville’s Black Pride, Legacy coordinated cross-network activity and HVTN 505 outreach efforts for the Vanderbilt Medical Center site in Nashville during general and Black Pride events. They collaborated around three main objectives: increasing cross network collaboration, specifically with the local ACTU site and ACTG CAB; increasing the engagement and participation of African Americans and Latino(a)s in HVTN and ACTG clinical trials (including transgender women); and collaborating with the faith community and clinical trial site to more effectively support each other around increasing the engagement and participation of African Americans and Latino(a)s in HVTN and ACTG clinical trials. Rev. Sanders has agreed to meet with both local sites in Nashville toward this end. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|---------------------------------------|---|----------|---|
| Objective #3: Continue to establish and implement clear definitions of synergy and cohesion between Legacy Project activities within the HVTN and HANC to ensure coordinated fiscal operations and maintain programmatic distinction while also ensuring singleness among external partners and collaborators. | | | | |
| Legacy Project Leadership Team | Develop definitions and expectations. | Clear distinction but also coordination of programmatic activities to assure efficient implementation of both HVTN and expanded network activities. | Ongoing. | Legacy contributed to Paula Frew, PhD's presentation at AIDS Vaccine 2010 which addressed the relevance of science and research to the lives of minority communities. During that retreat, Borris guided dialogue to include discussions of the importance of engaging minority communities around all networks establishing interconnected research advances, e.g. iPREX and CAPRISA. Recommendations will also reference challenges and possible solutions for pluripotent sites recruiting for multiple studies, when inclusion criteria are similar. In order to facilitate community and cross network collaboration to address multiple topics pertaining to engagement and participation of African American and Latino(a)s in clinical trials, Legacy worked with the site in Nashville to facilitate a community luncheon hosted by the Legacy Project which included representatives from the HVTN and ACTG sites, the faith community, as well as from local community based organizations (CBOs). These CBOs either currently work with the sites or could help increase the engagement and participation of the target population into clinical trials and biomedical research. Genevieve Meyer, Community Educator for the HVTN, is working with the Vanderbilt site to develop a work plan that will allow for continued progress around the three objectives. Support for ACTG CHPP program continued with a meeting with Emory staff providing crucial input on images and verbiage for recruitment brochures. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|--|----------|--|
| Objective #4: Expand the current Legacy Project Working Group (LPWG) to include membership and participation of all DAIDS-funded networks and establish regular communications with the working group. | | | | |
| Legacy Project Working Group | Invite at least 2 representatives from each of the 6 DAIDS-funded clinical trials networks to join the current LPWG. | Ensure inclusion of each network's priorities and establish relationships between the Legacy Project and each of the networks. | Ongoing. | Held monthly LPWG calls which focused on mission, structure, function and group membership. Expanded network representation in the LPWG includes: ACTG, HPTN, MTN, and INSIGHT. Representation from the HVTN remained the same. |
| Objective #5: Establish effective and efficient operating systems for the LPWG via Subcommittees. | | | | |
| Legacy Project Working Group | Establish and maintain LPWG Subcommittees; Vaccine Working Group, Communications Working Group, and the Behavioral Social Science Core. The Long Range Planning Task Force, which focuses on cohesive long range planning, which was previously established, continues its work. | Provide effective operations support for Legacy Project activities with maximum support for and from LPWG representatives. | Ongoing. | The LPWG held monthly calls which focused on issues pertaining to the structure of the group and subgroups. The LPWG formed the LPWG Strategic Planning Task Force which will be co-facilitated by Louis Graham, DrPH. His role in the process will be to field varying interests from LPSWG members, external collaborators and community members, as well as conduct an exhaustive literature review and co-author the strategic plan. He will work collaboratively with the Strategic Planning Task Force, Jeff Schouten and Damon Humes. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|---|--|----------|---|
| Objective #6: Establish a cross-network advisory group, the Legacy Project Women’s Caucus, composed of women leaders from around the country who represent low-income women, high risk women, women who are living in high risk populations, and women with experience working with these populations. | | | | |
| HANC Women’s HIV Research Collaborative formerly reported as Legacy Project Women’s Caucus | Establish the Legacy Project Women’s Caucus. The Legacy Women’s Caucus operates as an integral part of US domestic HIV prevention and therapeutic research effort focusing on women, especially those living in low-income, high risk areas, and other at-risk women. | The Legacy Women’s Caucus will operate as an advisory and collaborative entity to the Legacy Project providing important direction and guidance from the perspective of at-risk women and their representatives to the DAIDS HIV clinical research effort. | Ongoing. | Legacy Project staff engaged the concept of a National Women’s Consultation. Borris Powell enlisted the support of Dázon Dixon Diallo (Sisterlove Inc.), Dr. Stacey Little (AED), and Georgette King (FHI-HPTN). Kate Miller (HVTN Global CAB) and Georgette King have been installed as co-chairs. The group consists of representation from all six DAIDS networks. Initially, WHRC calls were scheduled monthly. The group will form the following subcommittees in Q3: HIV Treatment, Microbicide, HIV Positive Women (issues related to living positive), and Reproductive Health. To date, WHRC has completed a 3-tiered distribution of the Women’s Urgency Document (WUD) to DAIDS leadership, the HANC portal and public sites, and through social media networks including Facebook. WHRC representatives participated in the CFAR symposium on HIV and women (Chicago, IL). As follow up to establishing women’s research priorities in WUD, WHRC was successful in generating responses to the DAIDS blogs concerning network restructuring via a call to action. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|---|----------|---|
| Objective #7: Coordinate HANC Legacy Project activities with other HANC cross-network working group and projects. | | | | |
| Legacy Project Staff | Facilitate collaboration and harmonization among the various HANC working groups and projects. | Integration of the Legacy Project's focus on the populations most impacted by the HIV epidemic in the US into relevant HANC Working Groups for increased collaboration, harmonization and efficiency. | Ongoing. | Legacy Project staff established membership and participation on the HANC Behavioral Science Working Group, Site Coordinator Working Group, Community Partners, and the Communications Working Group. Paris Mullen represents Legacy on the HANC Communication Working Group Call, and the new Legacy Project Manager will participate on the Site Coordinator Working Group Call. Legacy Women and HANC Community Partners are in communication about addressing ethical issues focused on women and pregnancy in research. WHRC presented an overview of their goals and directions to CP. Negotiations are underway to convene a joint meeting of WHRC and CP on pregnancy and women in HIV research protocol. |
| Objective #8: Provide protocol support, especially where Legacy Project target populations are a major and or priority population for study enrollment. | | | | |
| Legacy Project Staff | Participate on protocol teams, where applicable, and/or in advisory, leadership or other roles. | Provide insight, advice and leadership from the Legacy Project perspective and represent the Legacy target populations. | Ongoing. | Borris Powell has active participation on HPTN 061 Black Caucus and is the Legacy Project representative on the HPTN 065 Community Advisory Group. This group recently completed an FAQ document for HPTN 065. Additionally, Borris was awarded a scholarship to attend CROI 2011. The scholarship provides opportunities to participate in the dissemination of new research data. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|---|----------|---|
| Objective #9: Collaboration between the HANC Legacy Project and historically African-American organizations | | | | |
| Legacy Project Staff | Strategies and activities to support this objective: <ul style="list-style-type: none"> The Legacy Project will work with leadership from these organizations. | The purpose would to develop a national campaign or strategy unique to each specific organization that would raise awareness and educate the African-American community about HIV prevention and treatment research, and engage in discussions about ongoing and planned HIV clinical trials. | On hold. | During this reporting period, LP staff engaged organizations during Black Pride celebrations. Additional collaborative work continued through funded pilot initiatives. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|---|----------|--|
| Objective #10: Collaboration with the Black AIDS Institute (BAI) sponsored Black Gay Men’s Network (BGMN) | | | | |
| Legacy Project Staff | Provide leadership and workshops regarding the importance of clinical trials in the local community. Facilitate cross network collaboration at BGMN events. Provide cross network information at BGMN events. Educate the network about the science of HIV/AIDS treatment and prevention as well as prevention and treatment technologies (provide leadership). | Establish a relationship with the Black Gay Men’s Network that will allow for an increase in the participation and engagement of African American men into DAIDS-funded clinical trials, as well as to educate this demographic of almost 800 African American men about the science and research involved in HIV/AIDS treatment and prevention. Provide DAIDS-funded cross-network exposure to the membership of the BGMN. | Ongoing | <p>As Leadership Development Chair for the BGMN, Paris has facilitated the distribution of cross network materials at BGMN regional events. He has coordinated recruitment and education opportunities for clinical trial sites at BGMN events. The Black Gay Men’s Network is planning their annual retreat in the Dominican Republic March 31st-April 4th. Paris has been responsible for producing the content and curriculum for the retreat. The workshops will address numerous topics as they pertain to black gay men and their identities. Paris has focused on the health and wellness component of the agenda. There will be workshops that focus on the importance of clinical trials and biomedical research in communities of color, as well as recent break-through advancements within research e.g.,: iPrEX, RV144 and CAPRISA 004.</p> <p>Chris Bland, Mobilization Manager for BAI, and Paris were elected as Regional Representatives for the US Western region of the BGMN. They will provide leadership for BGMN western regional committees. The BGMN steering committee has agreed to create a virtual presence for HIV/AIDS education by designating a portion of the BGMN website to HIV/AIDS research. Paris has gathered information and appropriate links for this section. Individuals will be able to learn about the Legacy Project, clinical trials, and how they can participate in research in their city. The network consists of almost 800 African American MSM. This effort aligns with BAI’s initiative to get all of the BGMN members to get tested and be aware of their HIV status.</p> |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|--|--|---------------|--|
| Objective #11: Legacy, National Alliance of State and Territorial AIDS Directors(NASTAD) and health department Initiative | | | | |
| Legacy Project Staff | Conduct a needs assessment of the current relationship between health departments, community based organizations and DAIDS-funded clinical trial sites. Develop a proposal to address that need, and establish a formal relationship with these organizations. | Establish cohesive and formal relationships with health departments, their contracted community-based organizations and local DAIDS-funded clinical trial sites to foster referrals to research opportunities for people who both test HIV-negative and positive at local VCT sites. | On going | This initiative will be developed in Q3. |
| Objective #12: Legacy and Creating Change collaboration. | | | | |
| Legacy Project Staff | Conduct an daylong health summit that will address disparities within the US healthcare system for LGBT communities. Provide opportunities and information that will equip individuals to impact US healthcare reform from grassroots and legislative levels. Provide education and discussion around LGBT health, Healthy People 2020, National HIV/AIDS Strategy and relevance of the 6 DAIDS-funded clinical trial networks and their trials. | Engaging and educate communities about DAIDS-funded networks. Provide opportunity for cross-network collaboration. Provide scientific training around new HIV technology and treatment and prevention modalities. Provide opportunities for community members to engage with and impact healthcare legislation in their local communities. . Educate and facilitate conversations about LGBT health disparities and standards of care. | February 2011 | Paris is managing and facilitating the creation of the 2011 Creating Change one day Health Institute. He conducts bi-monthly CC2011 Health Institute planning committee calls. The conference will take place February 2-6, 2011 in Minneapolis, MN. |

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held one call this quarter, in October, during which central IRBs were discussed. There were presentations by Renée Holt, RN, JD, MPH, Associate Director, Regulatory Affairs, HVTN and Nirupama Sista, PhD, Family Health International reviewing their experience with a central IRB for HVTN 505 and HPTN 065, respectively. The SWG met on October 13-14, 2010. HANC Director, Jeffrey Schouten made a presentation updating the SWG on HANC activities and projects over the past three years, since the prior HANC presentation to the SWG. DAIDS Director Carl Dieffenbach presented an update on network restructuring. The ACTG presented their TB research agenda and comments from external reviewers. The HPTN presented an update on HPTN 065 (TLC+). Community Partners presented their scientific priorities to the SWG. Following the SWG meeting, HANC helped organize a meeting of the Network Leaders with DAIDS Director Carl Dieffenbach to discuss network restructuring.

HANC organized 3 focused monthly conference calls with the six Network Principal Investigators and Co-PIs to address cross-cutting network leadership issues. HANC hosted a joint call on November 24, 2010 with the Network Leaders and the Communications WG to discuss the iPrEx results and implications for DAIDS network trials. HANC and DAIDS leadership also held monthly conference calls to collaboratively identify and address issues and share updates on activities.

HANC had two calls with OCSO leadership and was in frequent contact with OCSO to discuss the Protocol Costing Project and distribute policies in development to the Network Leadership Group and the core/operations centers. HANC held two calls with OPCRO leadership during which OPCRO presented updates on the DAIDS EAE Reporting Manual Version 2.0; ClinicalTrials.gov reporting; and OPCRO reorganization. HANC continued to work with OPCRO on the implementation of the “Manual for Expedited Reporting of Adverse Events (EAEs) to DAIDS”, version 2.0. HANC also continued to work with OPCRO and the networks and disseminated information about the new ClinicalTrials.gov results reporting requirements, and the resultant shift in responsibility to the networks for studies for which DAIDS is not the IND holder. HANC also updated OPCRO on the proceedings of the financial disclosure working group and the protocol costing project. OPCRO leadership also joined the DMC Harmonization Working Group October call to discuss the issue of data QC in the DAIDS-ES system, the production of reports from that data relative to reports generated by the SDMCs, and discuss RSC’s relationship and access to the data in the DAIDS-ES system. Sandy Butler of the RSC also participated in the calls with the DMC Harmonization Working Group. HANC Director Jeffrey Schouten also attended the NIAID Council Meeting on September 20, 2010 and the NIAID Town Hall meeting on October 26, 2010; both meetings which focused on the upcoming restructuring of the NIAID HIV/AIDS Clinical Trials Networks.

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 representatives to review the harmonized network Financial Disclosure/Conflict of Interest requirements, synchronize network financial disclosure reporting schedules, and evaluate the feasibility of developing a cross-network web-based reporting interface. | | | | |
| Network staff, OPCRO and OCSO | Develop a cross-network SOP addressing Financial Disclosure reporting requirements. | Harmonize the collection of financial disclosure data across the networks for their benefit and that of site investigators. Realize the cost-saving opportunity possible with a cross-network reporting system. | Completed SOP in Y4. Scope discussions are ongoing and will be completed by Q3. | The SOP was approved by Network Leaders in Q4 of Y4. The WG is now harmonizing the definition of members required to report and discussing the implementation of a cross-network online reporting system. |
| Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS representatives to identify and address priority site management issues. | | | | |
| Network Leaders, OCSO, OPCRO | Identify an evolving list of site management issues and opportunities. Work closely with network staff, OPCRO, OCSO and other DAIDS offices to address priority site management issues. | Improve communication and site operations. | Ongoing. | HANC conducted two calls with OPCRO and two calls with OCSO. HANC had frequent communication with OCSO to continue discussions around the Protocol Costing Project. |
| 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. | This Working Group has been discussing the implementation and training plans for v 2.0 of the DAIDS EAE Reporting Manual, the DAIDS Protocol Registration System, and site monitoring visits. The "Communications Handbook for Clinical Trials" was presented by Deborah Baron and Sarah Harlan to the Site Coordinators WG. Copies of the book were requested for a broader distribution to site coordinators across the networks. Interested WG members and book authors are working together to disseminate the book to sites, as needed. Issues that have emerged from the monthly calls have been communicated and resolved with OCSO. |

Training Coordination Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in 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. | Ongoing updates on the DAIDS Learning Management System (DLMS) which include new features and new trainings available were provided to the Committee. An overview of the OPCRO reorganization were provided by the Training, RET and ProPEP branch chiefs. Training requests were submitted via the Training Request Mechanism on the HANC portal for the ACTG and HVTN network meetings. An internal DAIDS WG was formed to discuss coordination of trainings and communication across the various contracts and will partner with the Committee to ask for input on the developed process. The HRCT planning team has been keeping the Committee regularly updated and involved with the deployment plan of the curriculum. See Training Objective #2 for details. |

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|---|--|---|------------------|---|
| Objective #2: Finalize, revise and deploy the HIV Research Counseling and Testing eLearning curriculum addressing risk reduction and adherence counseling in biomedical prevention and treatment trials. | | | | |
| Risk Reduction Counseling Training Development Working Group | Meet on regular calls to develop and review the training curriculum and ensure the project stays on track and within budget. | Improve the quality of risk reduction counseling in biomedical prevention and treatment trials. | August 2007-TBD. | The NIAID OD established a webpage on their website under the section of Resources for Researches: http://www.niaid.nih.gov/labsandresources/resources/Pages/default.aspx which will link to the DAIDS Learning Management System (DLMS) in December. This will allow DAIDS funded sites to access the curriculum online. The HRCT development team is still working towards making it available to external users outside of DAIDS. All 10 modules were reviewed and revised, in addition to the Training Resource Manual and Study Guide. The contractors who produced the curriculum made all technical changes necessary to the curriculum as required by the NIAID OD, i.e. 508 compliant, logos, colors etc and migrated it to the DLMS. The team is working with the networks on how to best roll-out the curriculum more broadly to CRS staff. The curriculum was rolled out during the HVTN and ACTG meetings in November. On-going biweekly check-in calls with all contractors and the HRCT development team continued as planned. Monthly HRCT Executive Committee calls continued as planned. |

Protocol Costing Project Objectives and Activities

| Group | Deliverables / Activities | Intended Impact | Timeline | Progress in Q2 |
|--|---|--|---------------------------------|---|
| Objective #1: Recommend to DAIDS method(s) for costing clinical trial protocols that could be applied to all Clinical Trial Units/Clinical Research Sites for all trials sponsored by DAIDS through any of its Clinical Trial Networks. | | | | |
| HANC, working with an ad hoc working group on protocol costing | Identify and recommend a uniform method(s) for estimating the costs for the participation of DAIDS CTU/CRSs in trials sponsored by any of the DAIDS clinical trial networks. Recommendations must take into account relevant issues impacting the CTU/CRSs and the Network Operation Centers, and build upon what is currently working well in the Networks. | To define methods for incorporation into the next round of Cooperative Agreements. | June 1, 2010-February 28, 2011. | Two meetings were held with the Working Group. The first, held in Seattle on September 13, 2010, included fiscal representatives from the six DAIDS Clinical Trial Networks and OCSO. The primary agenda for this meeting was to elucidate how each network currently costs protocols and to review the issues that should be addressed in the development of recommendations. A summary report for this meeting was prepared and circulated to the group in October. The report included post-meeting reflections on the project objectives that were solicited from the members via e-mail subsequent to the September meeting. On October 27, 2010 the group (this time including the network Program Officers, <i>three</i> representatives from OCSO, the NIAID Grants Management Officer, and additional site coordinators) met again in Arlington, Virginia. The focus of this meeting was to gain a better understanding of how the proposed CTU/CRS configuration in the new grant cycle might influence how protocols and site budgets for participating in protocols will be developed in the future. In addition, some broad direction for the recommendations – some stemming from feedback from the September 13 meeting – were considered and discussed. The results of these two meetings were used in informing the content of the report that contains the recommendations and describes the background and context of the recommendations. This report was drafted in November, and will be circulated for comments in the 3rd quarter. |