

HIV/AIDS Network Coordination Project

Year 5 Work Plan

June 1, 2010 – May 31, 2011

Introduction	1
Major Cross-Network Projects.....	2
Infrastructure and Administrative Support.....	4
Objectives and Activities by Area of Coordination	8
Behavioral Science Coordination Objectives and Activities	8
Communications.....	9
Community Coordination Objectives and Activities.....	10
Data Management Center Coordination Objectives and Activities	14
Evaluation Coordination Objectives and Activities	16
Laboratory Coordination Objectives and Activities.....	18
Legacy Project Objectives and Activities	21
Site Management & Logistics Coordination Objectives and Activities	24
Training Coordination Objectives and Activities	25

Introduction

The Office of HIV/AIDS Network Coordination (HANC) works with the six HIV/AIDS clinical trials networks funded by the Division of AIDS (DAIDS) of the U.S. National Institutes of Health (NIH) with the intent of creating a more integrated, collaborative and flexible research structure. The networks are an affiliated group of national and international medical research institutions and investigators that conduct clinical HIV/AIDS research to develop safe and effective drugs, prevention strategies, and HIV vaccines. They include the AIDS Clinical Trials Group (ACTG), the HIV Prevention Trials Network (HPTN), the HIV Vaccine Trials Network (HVTN), the International Maternal Pediatric Adolescent AIDS Clinical Trials group (IMPAACT), the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), and the Microbicide Trials Network (MTN).

HANC is based at the Fred Hutchinson Cancer Research Center in Seattle, Washington and has provided leadership and logistical support for cross-network coordination efforts since 2004. HANC’s mission is to support the science and operations of the networks by increasing efficiency and resource-sharing through coordination of critical activities across networks and with other research and advocacy partners. Efforts focus on: scientific leadership; site management and clinical trials logistics; behavioral science; communications; laboratory operations; the Legacy Project; training development and dissemination; harmonization of data management; development and application of consistent standards of performance evaluation; and facilitating effective community engagement in the research process. HANC is accountable in its activities to DAIDS and Network Leadership.

This HANC Work Plan outlines cross-network coordination objectives and activities for the period of June 1, 2010 - May 31, 2011. The document is intended to communicate and guide coordination efforts at a high level. Progress in meeting objectives will be monitored and communicated on a regular basis by HANC staff, as outlined on page 7.

Major Cross-Network Projects

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Infrastructure and Admin Support	HANC staff	Review website and portal user statistics and member survey data quarterly to inform HANC programmatic and portal improvements.	Improve communication and access to information to support decision-making and completion of cross-network objectives. Increase awareness of ongoing HANC coordination activities and potential new opportunities.	Ongoing.
Behavioral Science	Behavioral Science Working Group	Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science	Endeavor to maximize fiscal and scientific resources, reduce redundancies, improve cross-network communication and collaboration, and ensure that the best quality behavioral science is integrated into clinical trials.	Ongoing.
Behavioral Science	Behavioral Science Working Group	Create a repository of measures, data forms, and standardized core elements of interventions	Facilitate sharing of information and state-of-the-science practices.	Ongoing.
Behavioral Science	Behavioral Science Working Group	Collaborate on shared, permanent products such as white papers or manuscripts meetings, and workshops.	Leverage experiences and “lessons learned” from research for integration into network protocol planning. WG to host one full group F2F and two focus groups.	Ongoing.
Behavioral Science	HANC staff	Create “Behavioral Science Interest Group” alias for network-affiliated behavioral and social scientists.	Circulate notice of important tools, measures, CRFs, meeting notices, and articles.	Create alias Q1.
Communications	Communications WG	Follow-up on outcomes of May 2010 Communications Symposium Projects. Projects include the development of a Communications Resource Center on the HANC portal and the development of evaluation metrics.	Leverage network experience and expertise; collect communications tools and measures; and harmonize elements of the networks communications plans.	Ongoing.
Communications	IT Infrastructure WG	Provide opportunity for networks to share IT expertise, address challenges, and harmonize elements of websites.	Provide the networks a forum to discuss IT issues and new technology; improved navigation of network public sites.	Ongoing.
Community Coordination	Community Partners	Provide broad input and recommendations to DAIDS for upcoming network recompetition and restructuring process.	Improve the quality of community engagement with DAIDS, across Networks and with other Infections Disease groups.	Ongoing.
Community Coordination	Community Partners	Solicit and collate information on community engagement mechanisms that are best practices across sites and share this with networks, including posting CAB newsletters on the HANC website.	Networks.	Ongoing.

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Community Coordination	Community Training Working Group	Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to networks, sites, and other community groups.	Common community member understanding of basic concepts in HIV, TB, Malaria, and Hepatitis C diseases, clinical trials methodology, and CAB role. Improved training quality and consistency.	Ongoing.
Data Management	DMC Harmonization Working Group	Implement Information Technology Best Practice Standards at DAIDS Clinical Trials study sites/affiliated laboratories and 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 used by DMCs.	Ongoing.
Data Management	DMC Harmonization Working Group	Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization.	Electronic manifest files readable across multiple systems and reported back to SCHARP as part of an inventory data feed.	Ongoing.
Data Management	DMC Harmonization Working Group	Harmonization of MedDRA coding. The HANC-facilitated AIDS Defining Events WG will focus on the mapping of CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use.	Consistent MedDRA coding of adverse events across studies and a higher MedDRA coding standard.	Q1.
Data Management	DMC Harmonization Working Group, Lab PI/Manager and Training Committees	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.	Inform training plans and ensure that sites receive the data management training necessary to participate in clinical trials.	Ongoing.
Data Management	DMC Harmonization Working Group	Harmonize data definitions and standards for compatible all network use.	Formalize expectations among network and DMC staff and reduce duplicative systems.	Ongoing.
Evaluation	Evaluation Measurement Task Force and each Advisory Group	Work with each advisory group, CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes.	Develop evaluation metrics and processes to evaluate DAIDS and network success and identify opportunities for improvement.	Ongoing.
Laboratory Coordination	ACTG/IMPAACT LTC	Re-format Lab Processing Chart (LPC) template.	Make LPC more efficient and user-friendly.	Completion target end Q4 (June 2011)
Laboratory Coordination	ICAG	Draft/compile working group guidelines for communication and data flow.	Consistent quality control of PBMC Cryopreservation at network-affiliated laboratories.	Completion target end Q2 (Nov 2010)
Laboratory Coordination	PBMC SOP WG	Revise Cross-Network PBMC SOP.	Consistent PBMC processing at network labs.	Q1 (June-August 2010) Revise and approve SOP, post and mandate English version; Q2 (Sept-Nov 2010); submit CRS request for translations; Q3 Translate revised SOP; Q4 Post translations.

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Laboratory Coordination	Laboratory Focus Group	Conduct central validation and interfering substance studies of common rapid tests.	Validate common rapid tests to meet FDA requirements.	Completion target end of Q4 (June 2011)
Laboratory Coordination	TB Laboratory WG	Complete standard guidelines and template language for sample collection, transport and TB diagnostics for network protocols.	Efficient and effective drafting of network protocols in which TB diagnostics is an endpoint.	Completion target end of Q4 (June 2011)
Laboratory Coordination	Malaria Laboratory WG	Establish new Malaria Laboratory WG	Establish network of malaria diagnostics laboratories for use in network protocols.	Q1 (June-Aug 2010)
Legacy Project	Legacy Project Working Group	Build bridges of trust to overcome the history of abuse of people of color in research trials historically and build a new legacy of trust with these communities.	Increase enrollment of African Americans and Latinos/Latinas in HIV clinical research trials.	Ongoing.
Training	Training Committee	Identify and provide access to cross-network standardized training for high priority topic areas.	Provide training support to the sites.	Ongoing.
Training	HIV Research Counseling and Testing Development Group	Finalize, revise and deploy the HIV Research Counseling and Testing eLearning curriculum addressing risk reduction and adherence counseling in biomedical prevention and treatment trials.	Improve the quality of risk reduction and adherence counseling in biomedical prevention and treatment trials.	Q4 (Mar 2011-May 2011).
Site Management and Clinical Trials Logistics	Financial Disclosure Working Group	Harmonize meaning of "scope" in existing cross-network SOP. Consider creating a cross-network web database and submission form.	Eliminate redundant reporting requests and reduce the network's reporting costs.	Ongoing.
Site Management and Clinical Trials Logistics	Site Coordinators Working Group	Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks.	Address issues of common concern and harmonize policies and procedures regarding site-level operations.	Ongoing.

Infrastructure and Administrative Support

HANC Staff Role

HANC staff serve an administrative and project management role on each of the cross-network committees and working groups. As a working group or committee identifies areas of need or opportunity, HANC staff are responsible for developing and monitoring an action plan and documenting progress and challenges. HANC staff identify individuals to take on each task and encourage the group as they put in the time and sustained effort to complete the work, acknowledging that members participate in working groups and take on cross-network tasks voluntarily, above and beyond their full-time responsibilities within their primary organization. HANC staff are responsible for setting call and meeting agendas; drafting and distributing materials; coordinating logistics for and chairing teleconferences and meetings; taking minutes; and ensuring that action items are communicated, tracked and completed. HANC staff manage HANC portal team sites as a collaborative space for each working group, develop web-based tools, and train group members how to utilize them. HANC staff are an important conduit of information between different groups with potential shared interest or overlap in activity (e.g., ensuring that staff involved in

Training coordination communicate regularly with those involved in Laboratory Operations coordination regarding plans for Good Clinical Laboratory Practice training). Additionally, HANC staff are continuously identifying and promoting opportunities for cross-network coordination and collaboration. When they become aware of such opportunities they present them to the relevant working group, or in some cases bring them to the Network Leaders and DAIDS and form new working groups or taskforces as needed.

The HANC Public Website

The HANC public website (www.hanc.info) provides information and 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 web site.
- A dynamic announcement section on the home page for posting important notices. For example the CDC and WHO guidance and considerations on Influenza A (H1N1) and HIV infection which were posted as soon as they were distributed by the CDC and WHO.
- 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).
- A map showing locations of networks and research sites around the world.
- Information for laboratories, including PNL Contact Assignments and laboratory training videos.
- Resources and links to direct site and network staff regarding who to contact or where to find the information they are looking for.
- Library of Network and HANC newsletters.

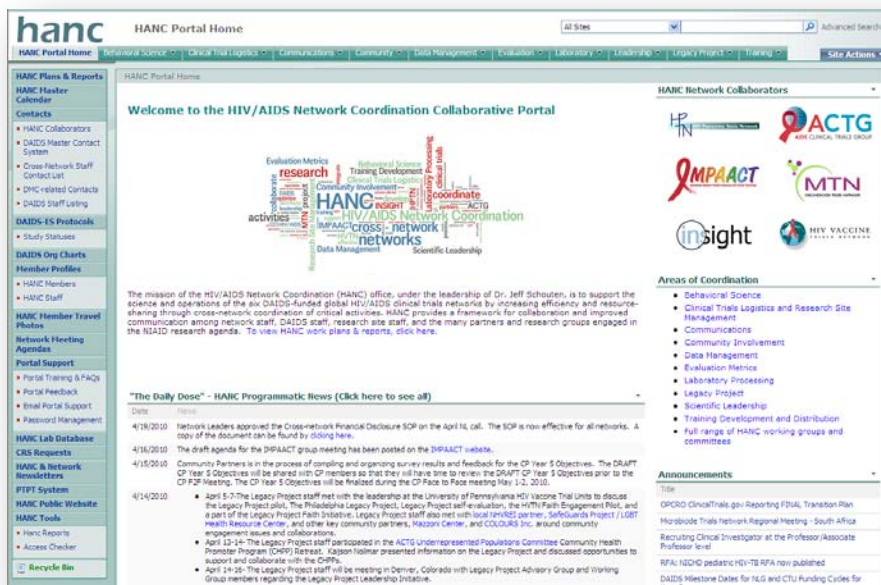


In Year 4 HANC began a major redesign of the HANC website. The project involved a thorough reorganization of the site, a new logo, and refreshed content. DAIDS and network staff provided feedback throughout the process. Year 5 will see ongoing adjustments, additions, and improvements to the new design.

The HANC Portal

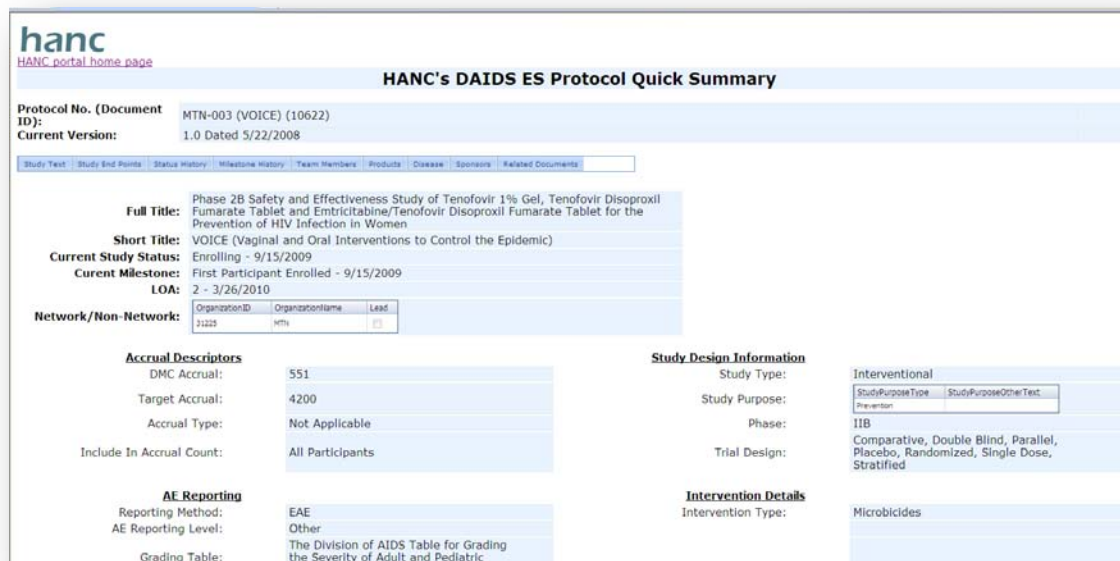
The HANC portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. The HANC portal includes document libraries; document development

and version control management tools; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; audience targeted contact lists; and a cross-network directory linked to the DAIDS-ES Master Contact system. At the beginning of Year 5, approximately 697 individuals have active and 113 labs have HANC portal user accounts and 50 secure team sites are used by specific cross-network working groups for collective document development, online discussion, and sharing of materials and information. HANC regularly solicits suggestions for the portal and updates the site accordingly.



HANC portal projects for 2010-2011 include:

- Upgrade to the SharePoint 2010 environment.
- Reviewing on demand user statistics and member survey data collected in Q4 of Year 4 to inform improvements to the HANC portal and team site content to better support the objectives of the project in Year 5. Over 200 portal users responded to the HANC portal user survey conducted in Q4 of Year 4.
- Maintaining web services that make the DAIDS-ES Master Contact system accessible to HANC portal users.
- Publicizing the recently added linkage to the DAIDS-ES protocol quick summary reports and all approved protocol documents, allowing ready access for all HANC portal users to this feature of the DAIDS-ES system via a web services feed.



- Expansion of the lab database to include equipment and platform inventories.
- Continued optimization of the Proficiency Testing Performance Tracking (PTPT) tool which captures laboratory proficiency testing data and manages the PTPT work flows so that appropriate contacts are notified of proficiency testing failures, multiple network responses to a failure are collected, and sites are notified in a single communication.
- HANC program staff provide programmatic updates on the “Daily Dose” announcement box.
- Ongoing expansion of the HANC Member Profile library.
- In Year 5, the Communications Working Group will develop the Communications Resource Center a repository of tools, presentations, articles, guides, best practices, and evaluation measures.

HANC Activity Updates

Clear progress updates from HANC will inform partners of cross-network activities undertaken, progress made and challenges encountered. HANC progress reports will be shared with stakeholders via:

- An Annual Work Plan and Quarterly HANC progress reports reviewed by the Network Leadership Group and DAIDS Leadership and posted on the HANC portal.
- An annual HANC progress report provided to NIAID Grants Management.
- HANC produces a bimonthly newsletter distributed to all portal users and posted on the home page of the HANC portal.
- HANC distributes an annual survey to all of HANC’s collaborators which evaluates HANC efforts and inform HANC of any changes needed.

HANC staff are available to provide updates or presentations as requested at all network group meetings or other meetings.

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 bi-monthly. “HANC Portal

101s” are now offered on a bi-monthly an ad hoc basis. HANC collaborators are invited to participate in a walk-through of portal/website resources and given the opportunity to learn more about the capabilities of the HANC collaborator portal. HANC will provide individualized trainings for OCSO and SDAC staff in Q1 of Year 5.

Outreach to Non-network Partners

In addition to working with DAIDS, network staff, affiliated labs, statistical and data management centers, site staff and community representatives, HANC collaborates with many other organizations. Some of the collaborative organizations include: the Adolescent Trials Network (ATN), AIDS.gov, AIDS Vaccine Advocacy Coalition (AVAC), Centers for Disease Control and Prevention (CDC), Forum for Collaborative HIV Research, Microbicide Media and Communications Initiative (MMCI), and the US Military HIV Research Program (MHRP). Members of these organizations contribute to working groups, attend HANC-facilitated meetings, participate on conference calls, and share Best Practices.

Clinical Research Support Contract

The HIV Clinical Research Support (CRS) contract between DAIDS and contract research organization PPD can be accessed by the networks to fund a variety of clinical research support tasks. Contracts vary from monitoring study conduct to providing simultaneous translation services for meetings. Networks request network-specific Clinical Research Support services from PPD through their designated point of contact at DAIDS. Requests for CRS services that apply across networks are made through HANC. HANC coordinates the development of cross-network CRS requests, submits them to the CRS project officer, tracks their progress, and liaises with DAIDS, PPD staff, and the networks involved. Tools on the HANC portal streamline CRS Request submission, tracking and status communication.

Objectives and Activities by Area of Coordination

Behavioral Science Coordination Objectives and Activities

The Behavioral Science Working Group is a trans-NIH Institute and cross-network committee formed as an outcome of the July 2008 HANC and the National Institute of Mental Health (NIMH) sponsored Prevention Adherence meeting. The Working Group is charged with ensuring that the DAIDS clinical trial networks benefit from state-of-the-science methods and procedures that optimize adherence to product and risk reduction counseling and minimize the risk of confounding user- and product failures. Further, the Behavioral Science Working Group endeavors to maximize fiscal and scientific resources, reduce redundancies, improve cross-network communication and collaboration, and ensure that the best quality behavioral science is integrated into clinical trials. The working group, formed in Q4 of Year 3, holds monthly teleconference calls.

Behavioral Science 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 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 Objective #3: Collate and analyze behavioral data elements across network studies.

Behavioral Science 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 and two focus groups in Year 5.

Behavioral Science 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 Objective #6: Improve information exchange among network-affiliated behavioral and social scientists. HANC will collate names of investigators associated with network working groups addressing behavioral issues. Create and manage a “Behavioral Science Interest Group” list serve whereby researchers can receive updates from the field, links to influential articles, network study updates, meeting information, etc.

Communications

The Communications Working Group was instituted in June of 2009. Since its formation, the group has considered a wide variety of issues affecting network clinical trials. The group is comprised of network communications professionals, community liaisons, and web masters. Much attention has been paid to new media and social networking tools; study results messaging; and understanding the networks’ respective communications strategies and policies. The IT Infrastructure Working Group provides a forum for network operations center staff, community liaisons, and data managers to share experiences with existing IT systems; share opinions about emerging technology; and to consider the changing IT landscape and its implications for managing complicated international clinical trials. These working groups have standing monthly calls.

Communications Objective #1: Develop cross-network strategic message guidelines and recommendations for study results dissemination.

Communications Objective #2: Consider ways to harmonize network communications strategies and external relations policies. Areas of interest include:

- Review and identify points of commonality across network websites
- 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.

Communications Objective #3: Develop a Communications Resource Center (CRC) on the HANC portal. The CRC will be available to all Communications Working Group members and invited guests. It will house a library of communications resources including: articles, guides, presentations, contact information, best practices, and white papers.

Communications Objective #4: Share IT- and communications-related developments across all areas of coordination. Possible areas of coordination 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.

Communications Objective #5: Review existing methods of evaluating communications efforts and consider which practices could be employed within the networks. Activities to support this objective 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.
- Collation of these resources for network use.
- Community education strategies.

Communications Objectives #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 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 Objective #8: Identify, implement, and maintain tools to improve cross-network communication. At present, HANC maintains the following portal resources:

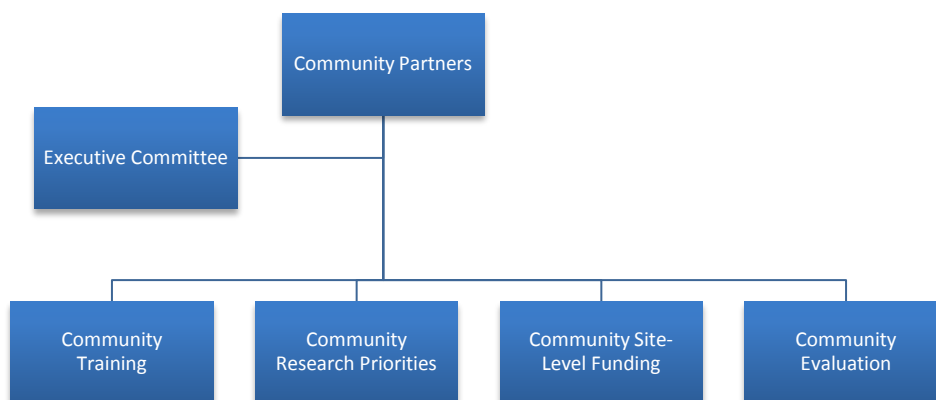
- DAIDS staff listing
- Data management related contact list
- Cross-network collaborator list
- Network newsletter library
- Archive of network meeting agendas.

Community Coordination Objectives and Activities

Since the 1990’s, community representatives associated with DAIDS-funded research networks and the networks have been working together to identify common issues and to learn new approaches and solutions from each other relating to community involvement in the DAIDS HIV clinical research enterprise. A Cross-CAB Working Group (CCWG) was formed in 2003, and HANC began providing facilitation for their calls shortly thereafter. In 2005, Cross-Network Best Practices for engaging community were developed by a group of community representatives and DAIDS. In June 2007 the CCWG was replaced by Community Partners (CP), an RFA-mandated body with a mission to enhance research by maximizing the effectiveness and benefits of community participation within and across the DAIDS-funded HIV clinical research networks.

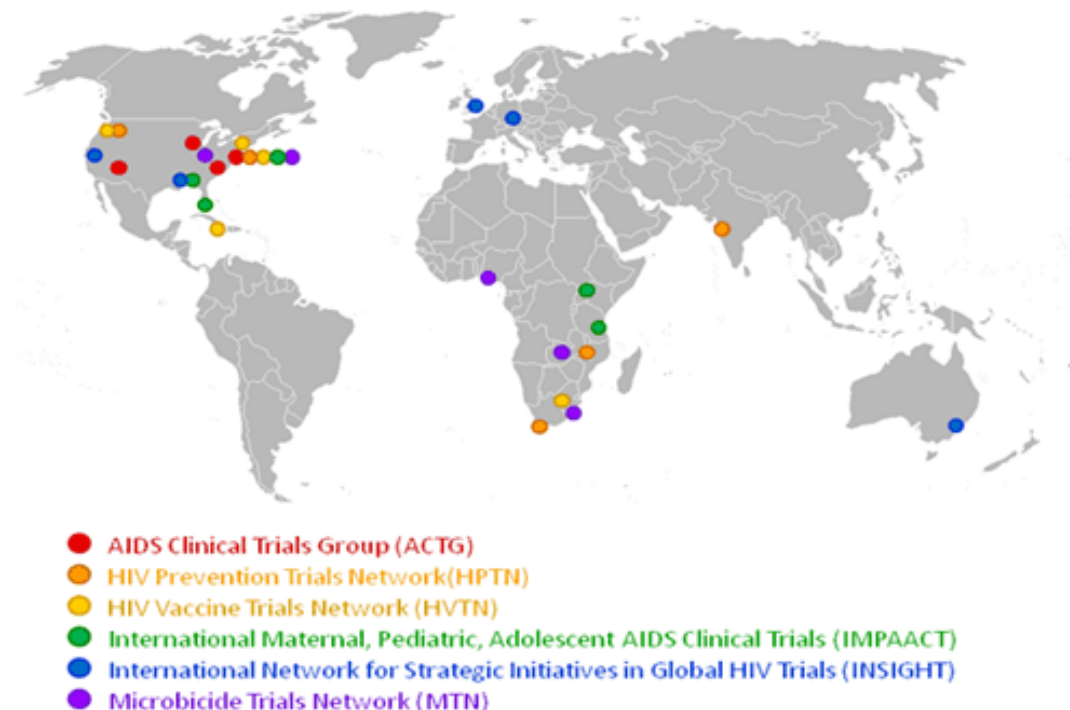
Community Partners and Working Groups

HANC supports Community Partners and the topic-specific working groups that it convenes. The HANC Community Partners Project Coordinator serves as a non-voting member of CP and provides group facilitation, project coordination, fiscal oversight, and administrative support.

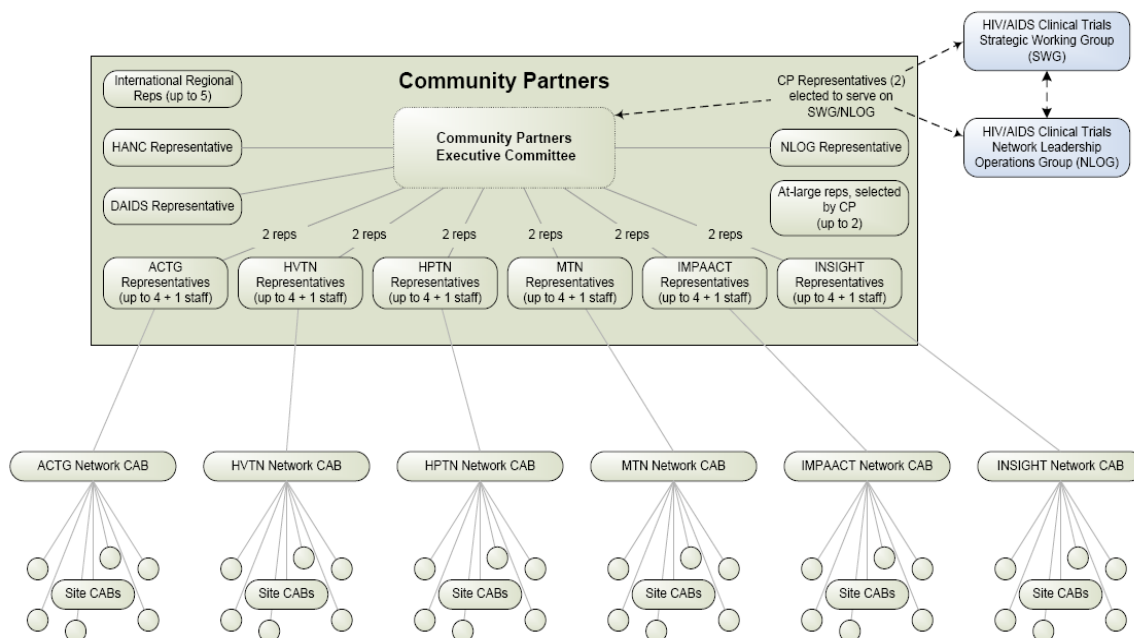


Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the DAIDS-sponsored HIV/AIDS clinical trials networks conduct research. CP represents cross-network community research needs and priorities to network leadership and DAIDS and is a venue for sharing resources and experiences across the networks, avoiding duplicative efforts, identifying and addressing challenges to participation in trials. CP is tasked with ensuring effective network representation and articulation of: scientific agenda priorities; ethical conduct of clinical trials; community education; communication and information dissemination; respect for community priorities; and continued community participation. CP members come from research sites from around the world. CP representatives sit on the Strategic Working Group and the Network Operations Leadership Group.

Map of Community Partners Members' Locations- May 2009



Community Partners Structure



The Community Partners Executive Committee is drawn from the general membership of Community Partners and is empowered to make decisions on behalf of and in the best interests of CP and its general membership in accordance with CP Organizational Guidelines.

The Community Training Working Group considers areas of community training common across networks and standardizes or develops materials that have broad application to community issues around HIV/AIDS clinical research and participation in trials.

The Community Site-Level Funding Working Group reviews site-level CAB funding and support to identify areas where funding and support mechanisms are working well and areas where there are problems or opportunities for improvement.

The Community Evaluation Working Group considers evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate Community Partners progress and impact and serves as an advisory group to the EMTF.

The Community Research Priorities Working Group considers areas of community research priorities across networks and makes recommendations to DAIDS and Network Leadership.

Community Coordination Objectives for Year 5

Community Partners Objective #1: Develop a community research priorities agenda.

Strategies and activities to support this objective:

- Identify Community Partners members to work on this project.

- Draft a clear written outline of the project scope, intent, timeline and evaluation criteria to determine if the project is successful.
- Implement the plan to develop the research agenda.

Community Partners 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.

Strategies and activities to support this objective:

- Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups.
- After completion of the training materials, the standardization process and impact of the initial cross-network CAB training module will be assessed and presented to CP. If there is consensus on the value added the working group will select additional priority topics to address using the same process.

Community Partners Objective #3: CP will consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate our progress and impact and serve as an advisory group to the EMTF.

Strategies and activities to support this objective:

- Develop a continuous quality improvement process for CP.
- Identify objective metrics and mechanisms for evaluating the impact of CP activities.
- Partner with DAIDS and EMTF and advise the EMTF on evaluation efforts as needed.

Community Partners 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.

Strategies and activities to support this objective:

- Research the current site/CAB funding structure to better understand how the system works.
- Partner with the network leadership to assess how site funding mechanisms have impacted community involvement at the network, CTU, and CRS levels.
- Based on analysis of that information identify expectations for CAB support and funding that can tie into cross-network community evaluation and make recommendations that are actionable to the Network Leaders and DAIDS.

Community Partners Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming network recompetition and restructuring process.

Strategies and activities to support this objective:

- Develop a clear, written outline of the project scope, intent, and timeline.
- Identify external domestic and international community groups and key stakeholders willing to provide input and recommendations to DAIDS for the network recompetition and restructuring process.
- Collaborate with networks to identify the most effective methods to solicit external community input.
- Gather and organize community input from existing network CABs and external groups regarding the recompetition and restructuring process and make actionable recommendations to DAIDS.

Community Partners Objective #6: Gather and collate information on community engagement mechanisms that are best practices across sites and share across networks.

Strategies and activities to support this objective:

- Develop a clear written outline of the project scope, intent, and timeline.
- Gather and organize existing network CAB newsletters to post on the HANC Website.

Data Management Center Coordination Objectives and Activities

The network Statistical and Data Management Centers (SDMCs) have identified key areas in which the sharing of expertise, resources, and procedures will strengthen the capacity and increase the efficiency of data management operations.

DMC Committees and Working Groups

HANC supports two active data management related working groups.

DMC Harmonization
Working Group

AIDS Defining Events
Working Group

The DMC Harmonization Working Group includes representatives from Frontier Science and Technology Research Foundation (FSTRF), the Statistical Center for AIDS Research and Prevention (SCHARP), and University of Minnesota. The Working Group meets on monthly teleconferences, and carries out activities to address cross-network data management coordination objectives.

AIDS Defining Events Working Group includes representatives from FSTRF, the Statistical and data Analysis Center, (SDAC), and SCHARP and meets on monthly teleconferences, and is charged with mapping CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use.

DMC Coordination Objectives for Year 5

DMC Coordination Objective #1: Implement Information Technology Best Practice Standards developed in Year 3 at DAIDS clinical trials study sites/affiliated laboratories and monitor infrastructure changes.

Strategies and activities to support this objective:

- The IT Best Practice standards document will be finalized and made available to all DAIDS Clinical Trials study sites and affiliated laboratories.
- Ongoing monitoring to ensure that infrastructure changes made by one group would not negatively impact the systems used by another IT. The monthly DMC Harmonization calls serve as a forum to discuss proposed changes.
- Consult with OTIS and OCSO and establish understanding of how the organizations will work with the networks.

DMC Coordination Objective #2: Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization

The three unique LIMS systems in use in the HVTN network (site affiliated labs use the Laboratory Data Management System (LDMS) as provided by FSTRF; the NICD lab in South Africa; and an endpoint lab use the HVTN LabWare LIMS. The DAIDS Repository (BBI/SeraCare) uses the DAIDS Repository BSI-II LIMS) and was designed to generate system-specific barcode label formats and shipping manifest file formats. Following successful efforts to modify LDMS to accept, import and export manifest files between HVTN LabWare and DAIDS BSI-II LIMS systems, SCHARP and FSTRF

propose to work with BBI/SeraCare and HVTN Labware to make additional changes to the manifest format, in order to complete Manifest Harmonization efforts.

Strategies and activities to support this objective:

- SCHARP and FSTRF will maintain code mappings across the LIMS systems as needed; and modify the specimen inventory data elements as requested by SCHARP to appropriately track and QA the data.
- SCHARP and FSTRF will work with each individual collaborating partner to ensure that previously identified common data elements are included and supported in electronic manifest files can be read across multiple systems and reported back to SCHARP as part of an inventory data feed.

DMC Coordination 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.

Strategies and activities to support this objective:

- The DMC Harmonization Working Group will collaborate with the cross-network Training Committee to identify and address data management training needs.

DMC Coordination Objective #4: Harmonization of MedDRA coding.

It would be advantageous in the long run to ensure that a consistent MedDRA coding of adverse events (e.g., a single reported verbatim has one corresponding MedDRA term) is maintained across network studies. The DMC working group will work with the DAIDS MedDRA consultant and DAIDS MedDRA Working Group (DMWG) towards harmonization of MedDRA coding. These efforts will also achieve a higher standard of MedDRA coding.

Strategies and activities to support this objective:

- The HANC-facilitated AIDS Defining Events will map CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use.
- Each network will designate a lead coder who will have completed formal training in MedDRA. This individual may be shared across networks.
- The lead coders are organized into the MedDRA Working Group, which is currently chaired by the DAIDS MedDRA consultant. Eventually it will be chaired by one of the lead coders, at which time the chair will be rotated annually. The Working Group conducts conference calls at least once per month, and will meet face-to-face at least once per year, rotating between network locations.
- The DMWG members developed a DAIDS MedDRA Terms Selection Guidelines document that is a supplement to the MSSO Terms Selection document. The group also developed the MedDRA Versioning Policy for DAIDS that outlines the procedures for updating the network databases with bi-yearly MSSO releases.
- The members of this working group will periodically exchange lists of MedDRA codes used for the first time which will be reviewed by the other coders in light of DAIDS enterprise coding policies. Disagreements in coding will be reported to the chair. The chair will collate the responses and redistribute to the entire working group for discussion and resolution during the monthly conference call. This group is also responsible for reviewing any nominations for the DAIDS-ES synonym list, collecting and reviewing change requests for possible submission to the MedDRA Maintenance and Support Services Organization (MSSO), as well as discussing other MedDRA-related issues and issue consensus statements as appropriate.

DMC Coordination Objective #5: Harmonize data definitions and standards for compatible all network use.

Strategies and activities to support this objective:

- In consultation with DAIDS and network operation centers, SCHARP, SDAC, FSTRF, University of Minnesota will collaborate to determine the feasibility of the project determine to whom, when, and how data elements should be harmonized.
- The group will draft a recommendations document to be circulated to DAIDS and Network Leadership for approval.

DMC Coordination Objective #6: Implement clinicaltrials.gov results reporting requirements.

Strategies and activities to support this objective:

- Identify policies and mechanisms for affected studies and existing data management systems.
- SCHARP and FSTRF will continue to communicate challenges and requests to DAIDS and Network Leaders. Experiences will be reported to the full DMC Working Group as needed.

DMC Coordination Objective #7: Harmonize clinical event collection policies and procedures to make recommendations on Adverse Events Reporting.

Strategies and activities to support this objective:

- Working group members will review vigilance reporting (FDA requirements and CTA agreements), pregnancy outcomes, the collection of non-AIDS defining events and toxicity tables, and develop in consultation with DAIDS recommendations for standardized cross-network policies and procedures.

DMC Coordination Objective #8: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS).

Strategies and activities to support this objective:

- Explore the formation of an Adverse Events Reporting Taskforce with representatives from the networks, SCHARP, FSTRF and DAIDS Office of Safety and Pharmacovigilance.
- Maintain ongoing dialogue with DAIDS staff regarding the development and requirements of the DAERS.
- Share experiences interfacing with the DAERS system on monthly DMC conference calls.

DMC Coordination Objective #10: Coordinate 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.

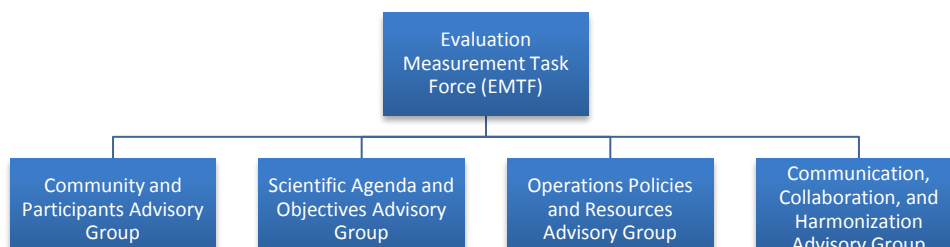
DMC Coordination Objective #11: Create an email alias for DMCs and network operation center staff. The list serve will be a vehicle to share important DAIDS updates and HANC working group activities.

Evaluation Coordination Objectives and Activities

Federal statutory and NIH mandates require DAIDS to conduct evaluations of its operations and programs. The Division of AIDS (DAIDS) began the implementation of an evaluation system for DAIDS and its HIV/AIDS clinical research networks in Year 3. This evaluation system has been designed to support the Division and its investigators in a cross-network evaluation that includes: identifying critical success factors; defining and implementing best practices; assessing progress towards achieving the mutual goals of scientific excellence; integration of therapeutics and prevention research; efficient use of resources; and effective collaboration. Evaluation data from this system, in conjunction with expert scientific review, may provide important feedback and will enhance DAIDS and its networks as they evolve. The scope of the evaluation of the DAIDS HIV clinical research enterprise includes DAIDS itself, the DAIDS-funded clinical trials networks and sites, and HANC.

Evaluation Committees and Working Groups

HANC supports the Evaluation Measurement Task Force and four related advisory groups.



The Evaluation Measurement Task Force (EMTF) is comprised of representatives from each of the networks, DAIDS and HANC. The task force will provide detailed, technical input about potential measures, data sources and tools to be considered for use in the development of the evaluation system plan.

Operations, Policies and Resources Advisory Group focuses on administrative policies, funder issues, process efficiency, and site capacity. Included in the scope of this advisory group is how to evaluate: 1) the efficiency of policies and procedures in the conduct of high quality science; 2) the provision and use of resources; and 3) the capacity of clinical research sites.

Community and Participants Advisory Group focuses on the importance of community involvement at all levels and at critical milestones in study development and implementation. Included in the scope of this advisory group is how to evaluate the ways the network research enterprise: 1) addresses questions of relevance to the communities and trial participants; 2) produces results (including answers to questions) that may lead to preventions and treatments that can practically and affordably be made available to the study participants and their communities; and 3) provides adequate support for community participation and education.

Scientific Agenda and Objectives Advisory Group focuses on how the networks specifically, and the DAIDS HIV clinical research enterprise as a whole, identify their research priorities, how they identify prevention and treatment strategies for HIV/AIDS leading to fewer new infections, and how their efforts assure progress on the pathway to reduced morbidity and mortality. Included in the scope of this advisory group is how to evaluate aspects of the pipeline through which each study passes starting with the setting of the scientific agenda, progressing through study implementation, dissemination and impact.

Communication, Collaboration and Harmonization Advisory Group focuses on the collaboration and communication within and between networks and between DAIDS and the networks and sites. Included in the scope of this advisory group is how to evaluate: 1) collaboration activities at the scientific and operational levels; 2) the restructuring principles of efficiency, coordination, and integration; 3) the function of HANC; and 4) the coordination and maximization of research opportunities.

Evaluation Coordination Objectives for Year 5

Primary evaluation coordination objective for 2010-2011 include:

Evaluation Objective #1: Work with each advisory group, CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes.

Strategies and activities to support this objective:

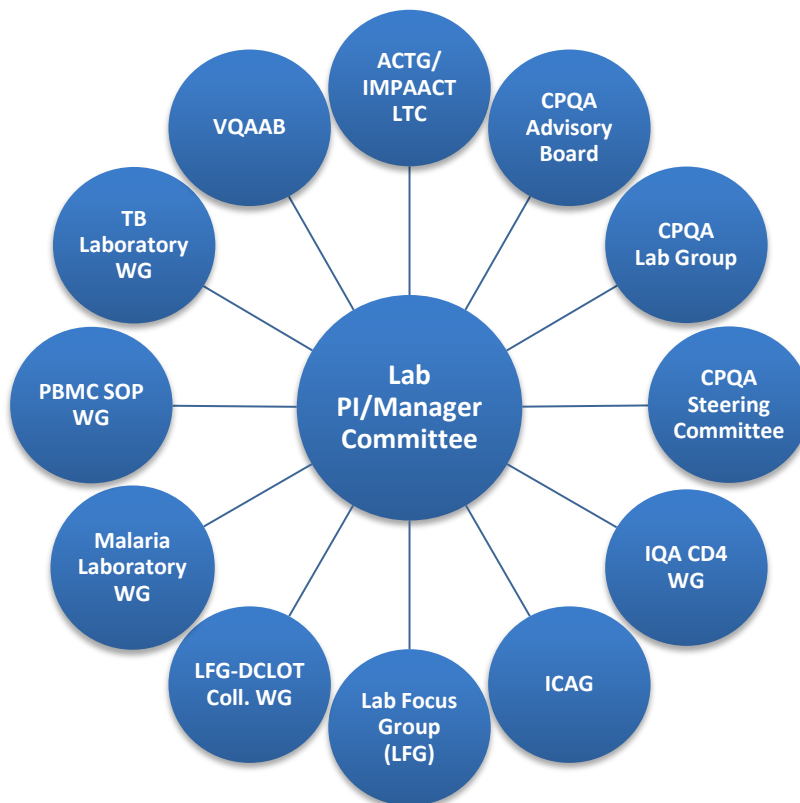
- HANC to hold monthly calls with each advisory group and CSI to facilitate the evaluation activities that address each advisory group’s scope.
- HANC to participate in bi-weekly calls with DAIDS and CSI as a way share the progress of each advisory group and provide feedback as necessary in regards to the overall project.

- HANC to broaden representation of the advisory groups in order to ensure adequate representation across the networks and avoid duplication of other ongoing evaluation efforts.
- HANC to provide leadership and the clinical context of the ongoing evaluation activities.

Laboratory Coordination Objectives and Activities

Laboratory Committees and Working Groups

HANC supports 13 active laboratory working groups.



The Laboratory PI/Manager Committee includes Network Lab PIs, Lab Managers and DAIDS Clinical Laboratory Oversight Team (DCLLOT) members, NICHD, statistical data management centers, and quality assurance contractors who meet on ad hoc teleconferences to serve as a central communication center for the other laboratory working groups and committees. The Lab PI/Manager Committee receives updates from the various laboratory working groups and discusses issues raised by them.

The ACTG/IMPAACT Laboratory Technologist Committee is a join ACTG/IMPAACT committee. Members serve on protocol teams and provide those teams with technical expertise in the development of the laboratory components of protocols as well as standardizing the handling, processing, labeling, and storage of clinical specimens across all clinical sites and laboratories. HANC coordinates specific projects and give technical support to the committee’s HANC portal team site, which contains a variety of development and resource document libraries and a discussion board to facilitate distance communication.

The Clinical Pharmacology Quality Assurance (CPQA) Advisory Board serves as a forum for the networks to communicate their pharmacology quality assurance needs to the PQA program and provides oversight for the activities of the CPQA. The CPQA Advisory Board includes the directors of the Network Pharmacology Specialty Laboratories, DAIDS, and the CPQA who meet during quarterly teleconferences.

The CPQA Lab Group serves as a forum for communications between the CPQA program and Pharmacology Laboratories regarding key information about each program area's activity and the laboratories' anticipated participation in the activity. The laboratories provide feedback and dialogue regarding pharmacology quality assurance activities and needs during bimonthly teleconferences.

The CPQA Steering Committee receives direction and provides feedback regarding operating status of the CPQA program areas. The CPQA Steering Committee includes representation from the CPQA, data management center, and sub-contractors.

The Immunology Quality Assurance (IQA) CD4 Working Group addresses CD4 proficiency testing issues at non-US laboratories, quality management, instrument validation, and integrity of CD4 data to protect patient/study populations. This is accomplished through monthly teleconferences which includes representatives from ACTG, IMPAACT, HPTN, HVTN, MTN, NICHD, DAIDS, SMILE, UK NEQAS, and the IQA.

The IQA PBMC Cryopreservation Proficiency Testing Advisory Group (ICAG) collaborates with the IQA to develop and implement a PBMC cryopreservation proficiency testing program for US and non-US laboratories, and quality control of cryopreserved PBMC samples at the Biomedical Research Institute (BRI) repository on monthly teleconference calls. ICAG includes statisticians and representatives of ACTG, IMPAACT, DAIDS, FSTRF, Westat, NICHD, and the IQA.

The Lab Focus Group (LFG) includes the network laboratory and operations staff and meets once or twice per month to do much of the detailed background, document development, and follow-up work to complete projects and tasks that address laboratory training, operations, and support issues that apply across networks.

The LFG-DCLLOT Collaborative Working Group includes members of the LFG and DCLLOT in order to facilitate communication on specific topics as needed. Calls are held on an ad hoc basis.

The Malaria Laboratory Working Group will include representatives of ACTG, HPTN, IMPAACT, DAIDS and SMILE. The group will be established during Year 5.

The PBMC SOP Working Group is charged with developing, implementing, reviewing, and revising the Cross-Network PBMC Processing SOP. The PBMC SOP WG includes representatives of ACTG, IMPAACT, HPTN, HVTN, MTN, CHAVI, DAIDS and the IQA and meets during ad hoc teleconferences.

The TB Laboratory Working Group includes SMILE, DAIDS, IMPAACT and ACTG members and identifies and evaluates international TB diagnostic laboratories for participation in clinical trials with TB diagnostic endpoints, and develops standards for specimen collection and transport and TB diagnostics for network protocols.

The Virology Quality Assurance Advisory Board (VQAAB) addresses virology proficiency testing issues identified by Virology Quality Assurance (VQA) and other VQAAB members during monthly teleconferences. The VQAAB includes representatives of ACTG, IMPAACT, HPTN, HVTN, DAIDS, the VQA, and sub-contractors.

Laboratory Coordination Objectives for Year 4

Laboratory Coordination Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.

Strategies and activities to support this objective:

- A face-to-face meeting will be scheduled as needed to bring together the Laboratory PIs, Laboratory Managers, DAIDS Laboratory program staff, and key contractors/partners.
- Cross-Network Laboratory PI/Manager Committee and LFG teleconferences will provide a forum for identifying, discussing and resolving issues, sharing information, and identifying new projects and tasks to be included in cross-network laboratory coordination efforts.

- LFG/DCLLOT teleconferences will facilitate communication among network laboratories and DCLLOT regarding DAIDS policies and procedures that apply to network laboratory activities.
- The HANC public website “Laboratory Resources” section will be increasingly utilized to share cross-network information with the sites and labs.
- The laboratory database on the HANC portal will be further developed to contain additional parameters useful to the network laboratories until such time that they are captured in the DAIDS-ES system.
- Various laboratory working groups will coordinate the development of questionnaires for collecting laboratory information for cross-network use.
- HANC staff will maintain a team site on the HANC portal for each working group for information sharing and collaborative document development.
- HANC staff will continue to solicit and publish HANC member profiles to support working group rapport and communication.

Laboratory Coordination 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 NIAID (DAIDS) funded and/or sponsored site laboratories by improving communication and timely access to relevant information.

Strategies and activities to support this objective:

- The cross-network QA working groups including the CPQA groups, IQA CD4 WG, ICAG, Malaria Laboratory WG, TB Laboratory WG, and VQAAB will continue to provide a forum for the review and discussion of program-specific proficiency testing results on regular teleconference calls.
- Cross-network QA working groups and the LFG (for safety QA) will develop, review, and/or modify as needed guidelines for laboratory quality management including performance criteria and mechanisms for restricting protocol testing based on poor proficiency testing performance and guidelines for data and communication flow.
- ICAG will complete, test and implement plan for quality control of cryopreserved PBMC that are sent to the Biomedical Research Institute (BRI) repository.
- ICAG will complete policies and procedures of the IQA Cryopreservation PT Program and draft/compile standard communications documents for communication with labs
- ICAG will formulate a communication scheme and document it (ICAG Working Group Guidelines for Communication and Data Flow) as part of the TQM document.
- ICAG will develop guidelines for the development of back-up plans for PBMC processing laboratories
- The LFG will continue to utilize online portal tools to review and track proficiency testing results and coordinate feedback to network site-affiliated laboratories for international laboratories. This will allow for timely coordinated responses to potential problems, transparent tracking of issue resolution, and the ability to track and respond to trends over time.
- HANC will continue to upgrade and modify these online tools as necessary.
- The VQAAB will continue to review HIV RNA validation reports of data from laboratories that have newly installed HIV RNA assays.

Laboratory Coordination 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.

Strategies and activities to support this objective:

- Identify where economies of scale can be achieved by sharing resources, technician training opportunities, laboratories, etc. and address this opportunities in existing or new working groups.

- Facilitate use of the DAIDS Learning Management System (DLMS) to deliver and/or track laboratory training modules and manage training at the site levels.
- Revise the Cross-Network PBMC Processing SOP for use at network laboratories.
- Coordinate the negotiation of memoranda of understanding and/or purchasing/service agreements with suppliers as necessary.
- Develop a coordinated system for collecting and updating instrument/method information from laboratories.

Laboratory Coordination 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.

Strategies and activities to support this objective:

- Identify, evaluate and support TB laboratories that can serve as regional centers of excellence, including those that can:
 - Perform technically challenging TB testing in network clinical studies.
 - Conduct evaluations of TB diagnostic methods for use in HIV-positive and smear-negative study participants, including the evaluation of test characteristics and performance.
 - Serve as regional training resources.
 - Implement standard guidelines for laboratory personnel safety.
- Be a resource to network protocol teams:
 - Maintain a list of US and non-US labs with reliable TB diagnostic capacity as a resource for networks and their partners when conducting studies when TB is a component.
 - Recommend laboratories for participation in studies.
 - Review proposed methods and providing technical support (e.g. SOPs).
 - Propose and implement relevant EQA and QC approaches to ensure the quality of study data.
 - Review TB component of study-specific MOPs to include guidance on sample acquisition and processing prior to shipment to testing laboratories.
 - Draft/compile and implement standard guidelines for sample collection, transport and diagnostics.
 - Coordinate comparative evaluations of TB laboratory methods.
 - Explore opportunities for the development and validation of point-of care TB laboratory assays.

Laboratory Coordination Objective #5: Collaborate among the networks, HANC, DAIDS and SMILE to establish a Malaria Laboratory Working Group.

Legacy Project Objectives and Activities

The HANC expanded cross-network Legacy Project, begun in October 2009, builds on the efforts and successes of the HVTN Legacy Project, a program that established a blueprint for increasing engagement and collaborative efforts between the populations most impacted and researchers and their institutions while addressing historic inequities to overcome the demographic and socio-economic disparities that threaten all DAIDS-funded research and ultimately the communities and populations they serve. Extensive work on partnership and relationship development, both internal among DAIDS funded networks and external ensures that the work of the Legacy Project

impacts DAIDS-funded research, while ensuring the commitment of capacity building and infrastructure development within the communities and populations most impacted by the domestic HIV epidemic.

The Legacy Project's operating principles are:

- **Inclusion:** All HIV research must include racial and ethnic populations in numbers that reflect their level of risk, as well as their representation in the HIV epidemic.
- **Leadership:** Identify those leaders who can guide DAIDS-funded networks to address barriers, especially socio-cultural, psychological and structural barriers to clinical trial participation in conjunction with other work to eliminate health disparities.
- **Cultural Competency / Responsiveness:** Identify and address site levels of cultural competency / responsiveness and provide programs to improve proficiency of current staff and resources to increase diversity of staff.

Legacy Project Objective #1: Continue the development of the HANC cross-network Legacy Project.

Strategies and activities to support this objective:

- Enhance cultural competency within the networks and build relationships of trust with African-American and Latino/Latina communities within the U.S. to enhance participation of African-Americans, Latinos, and Latinas in network trials

Legacy Project 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.

Strategies and activities to support this objective:

- Ensure collaboration with the HVTN Legacy Project and the HANC cross-network Legacy Project.

Legacy Project 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.

Strategies and activities to support this objective:

- Clear distinction but also coordination of programmatic activities to ensure efficient implementation of both HVTN and the expanded Legacy Project cross-network activities.

Legacy Project 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.

Strategies and activities to support this objective:

- Ensure inclusion of each network's priorities and establish an efficient linkage between the Legacy Project and each of the networks.

Legacy Project Objective #5: Establish effective and efficient operating systems for the LPWG via Subcommittees.

Strategies and activities to support this objective:

- Provide effective operations support for Legacy Project activities with maximum participation, support for and from LPWG representatives.

Legacy Project 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, at-risk women, women who are living in high risk populations, or women experienced working with these populations.

Strategies and activities to support this objective:

- 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.

Legacy Project Objective #7: Coordinate HANC Legacy Project activities with other HANC cross-network working group and projects.

Strategies and activities to support this objective:

- 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. The most relevant HANC Working Groups include the Behavioral Sciences Working Group, the Communications Working Group, Site Coordinators Working Group and Community Partners.

Legacy Project Objective #8: Provide protocol support, especially where Legacy Project target populations are a major or priority population for study enrollment.

Strategies and activities to support this objective:

- Provide insight, advice and leadership from the Legacy Project perspective and representing the Legacy target populations working both with protocol teams and clinical research sites.

Legacy Project Objective #9: Collaboration between the HANC Legacy Project and historically African-American Organizations.

Strategies and activities to support this objective:

- The Legacy Project will work with the 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.

Network Leadership

NLOG

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 quarterly calls include the participation of representatives from 18 NIH Institutes and Centers and provide a venue for cross-network as well as trans-Institute information sharing and discussion. HANC solicits information from the networks, NIH representatives, and other partners to bring forward and organizes and facilitates the NLOG quarterly teleconferences.

SWG

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 DAIDS-funded 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 times a year by DAIDS to review and discuss scientific plans, progress and opportunities, specific protocols and cross-network issues. The HANC Director and two Community Partner representatives participate in the SWG meetings which are organized and facilitated by DAIDS.

Network Leaders and DAIDS

HANC organizes focused monthly and ad hoc conference calls with the leadership of the six HIV Clinical Trials Networks 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, a monthly call with the leadership of the Safety and Pharmacovigilance Team and a bimonthly call with the leadership of OSCO and OPCRO.

Site Management & Logistics Coordination Objectives and Activities

Site management and oversight, harmonization of clinical trial logistics and operations at the site level across the networks has been identified as an area of high priority for coordination.

Site Management Working Groups

Site management and clinical trials logistics issues are diverse and addressing each issue is likely to require involving a different group of individuals with specific expertise. Network and DAIDS Leadership and HANC will work closely with the OCSO and OPCRO offices at DAIDS to identify issues and identify appropriate individuals to involve in ad hoc working groups that are likely to be convened on a short-term basis to address specific issues. Additionally, HANC facilitates a cross-network Site Coordinators Working Group formed in Year 4 to address issues of common concern and harmonize policies and procedures regarding site-level operations.

Site Management and Clinical Trials Logistics Coordination Objectives for Year 5

Site Management and Clinical Trials Logistics 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.

Site Management and Clinical Trials Logistics Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS representatives to identify and address priority site management issues.

Strategies and activities to support this objective:

- Network Leaders, OCSO, OPCRO and other stakeholders will identify an evolving list of site management issues and opportunities to better coordinate their respective efforts. Topics may include such issues as: reducing confusion around site monitoring by clarifying site new performance monitoring policies; clarifying DAIDS and networks respective responsibilities; harmonizing site establishment processes; and address issues relevant to site budgets.
- Hold monthly calls with HANC and OCSO leadership to facilitate communication and coordination of site level activities.
- Hold quarterly calls with HANC, OCSO and OPCRO leadership to facilitate communication and coordination of site level activities.
- Convene topic-specific working groups on an ad hoc basis to address site level issues.

Site Management and Clinical Trials Logistics Objective 3: Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks.

Strategies and activities to support this objective:

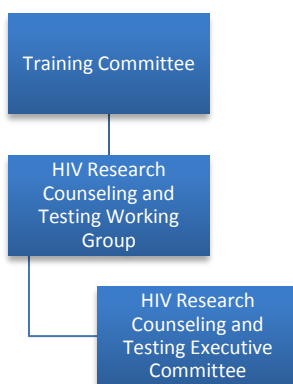
- Hold monthly site coordinator teleconferences dedicated to address significant site issues common across the networks.

- Discuss issues that emerge from the Site Coordinator WG with the Network Leaders, core/operations centers, OCSO and/or OPCRO as appropriate.
- Provide site-level perspective to DAIDS and or core/operations centers on new or revised policies and procedures.
- Share IT Best Practices document with the Site Coordinators Working group (See DMC Coordination Objective #1- page 14).

Training Coordination Objectives and Activities

Training Committees and Working Groups

HANC facilitates three cross-network training groups.



The Training Committee identifies and addresses cross-network core operations center and clinical trial unit training needs. The committee serves as the main point of contact for training related requests and issues, and consists of 35 invitees/members from DAIDS, PPD, FSTRF, Community Partners, MHRP, SCHARP, and each network.

The HIV Research Counseling and Testing (HRCT) Working Group convened when development of HIV Research Counseling and Testing training was identified as a high priority training topic area during the December 2006 Training Committee meeting. With HANC support, Dr. Jonathan Fuchs agreed to chair a working group composed of members across the networks with expertise in risk reduction counseling in biomedical prevention and treatment trials. With finalization of the original eight modules developed by the WG (in English and Spanish), the HRCT planning group is now planning for deployment and finalizing production of two new modules supported by the NIMH (also in English and Spanish).

The HIV Research Counseling and Testing Executive Committee consists of members from DAIDS, PPD, HANC and the chair of the HRCT. This committee holds monthly calls which will review revisions to the curriculum and develop the deployment plan.

Training Coordination Objectives for Year 4

Training Coordination Objective #1: Identify and provide access to cross-network standardized training for high priority topic areas.

Strategies and activities to support this objective:

- Monthly cross-network training committee teleconferences provide a forum for identifying and discussing training needs and ways to provide access to trainings.
- The HANC portal provides a team site for the Training Committee and each Working Group. The team sites support information sharing, list training announcements, provide a training request mechanism for the

network training representatives to submit on an as needed basis for their upcoming network meetings or based on a site request, contain a training documents library, training topics blog, and allows for collaborative document development. Additional tools will be developed depending on group needs.

- The HANC public website provides CTU/CRS staff with information on upcoming training events and training resources available in various formats.
- DAIDS to continue sharing evaluation reports for past DRTes and update the committee as new trainings are modified or become available.
- HANC will facilitate communications about training options available on the DLMS.

Training Coordination 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.

Strategies and activities to support this objective:

- The HIV Research Counseling and Testing development team will continue to meet via teleconference to discuss revisions and updates to the curriculum for deployment.
- The HIV Research Counseling and Testing development team will engage the Training Committee in continuing development of the deployment plan.

The HIV Research Counseling and Testing Executive committee will continue to meet via teleconference to supervise the deployment of the eLearning curriculum to the DLMS.