

HIV/AIDS Network Coordination Year 3 Work Plan

June 1, 2008 – May 31, 2009

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Introduction

The HIV/AIDS Network Coordination (HANC) project 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).

The HANC project 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 research logistics; laboratory operations; 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, 2008 - May 31, 2009. 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 in section V.

Cross-Network Projects and Deliverables Timeline

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Infrastructure and Admin Support	HANC staff	Review user statistics and member survey data collected in Q4 of Year 2 to inform HANC Portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives.	Begin work in Q1 (June-Aug 08) with redesign complete by end of Q2 (Nov 08)
Laboratory Coordination	Lab Focus Group, Lab PI/Manager Committee	Review the TQM proposal and revise as necessary before taking the next steps toward full implementation.	Consistent clear guidelines for responsibilities, monitoring, data and communication flow across and within QA areas.	Q1 (Aug 08) review with LFG; Q2 (Sept 08) present to Lab PI/Mgr Committee; Q3 (Dec 08) Finalize
Laboratory Coordination	PBMC Cryo QA Working Group	Develop IQA intervention, corrective action, remediation and training approach; formulate communication scheme.	Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories.	Completion target Q3 (Dec 08)
Laboratory Coordination	Viral Load Validation WG	Implement the cross-network Viral Load Validation template and SOP developed in Year 2	Consistent viral load validation at Network-affiliated laboratories.	Completion target end Q4 (June 09)
Laboratory Coordination	Cryo Optimization Study Working Group	Complete study for optimization of PBMC Cryopreservation Protocol, develop a PBMC Cryopreservation SOP based on the data generated, and implement the SOP.	Consistent and optimized procedures for the cryopreservation of PBMCs at Network-affiliated laboratories.	Completion target end Q4 (June 09)
Community Coordination	Community Partners	Develop a community science research agenda.	TBD	TBD
Community Coordination	Community Recommendations Working Group	Finalize and disseminate the recommendations on providing community input into the planning and implementation of research activities.	Improved community input into the planning and implementation of research activities.	Q1, target completion Q2 (Nov 08)
Community Coordination	Community Training Working Group	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.	Common CAB member understanding of basic concepts in HIV disease, clinical trials methodology, and CAB role. Improved training quality and consistency.	Materials sharing ongoing; Development of standardized module beginning in Q1
Community Coordination	Community Partners	Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact.	Clear measures to demonstrate the value of Community Partners. Data to identify opportunities to increase CP effectiveness.	TBD
Community Coordination	Community Partners	Review site-level CAB funding in the current grant period. Identify areas where support mechanisms are working well and opportunities for improvement	Adequate site-level CAB support.	TBD

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Training	Risk Reduction Counseling Training Working Group	Complete the development of training materials addressing risk reduction counseling in biomedical prevention and treatment trials.	Improve the quality of risk reduction counseling in biomedical prevention and treatment trials.	Q3 (Dec 08-Feb 09)
Training	Training Committee	Identify ways to strategically address implementing a sustainable training program.	Provide financially and operationally sustainable training support to sites.	Ongoing
Training	Admin-Fiscal Training working group	Review the grants management on-line trainings recently made available by the OIEA and identify gaps where additional admin-fiscal training development is needed.	To avoid duplication of training materials created by the OIEA and provide a comprehensive grants management training curricula to all CTU/CRS.	TBD
Site Management and Clinical Trials Logistics	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.	Begin work in Q2 (Sept 08)
Site Management and Clinical Trials Logistics	Network staff, OPCRO and OCSO	Develop a communication plan and process flow for how site management issues will be identified, addressed, and resolution communicated to relevant stakeholders.	Increase the efficiency and speed of resolving site management issues.	Begin work in Q2 (Sept 08)
Site Management and Clinical Trials Logistics	HANC staff	Partner with the National Institute of Mental Health to hold a one and one-half day face-to-face meeting in Bethesda, MD to bring together the DAIDS-funded HIV/AIDS clinical trials networks and other partners to address critical cross-cutting issues in prevention adherence.	Explore lessons learned from treatment adherence and to apply them to increase adherence in HIV prevention in biomedical and other trials.	Q1 - meeting to be held July 08. Follow-up activities may be ongoing.
Data Management	DMC Harmonization Working Group	Implement Information Technology Best Practice Standards developed in Year 2 at DAIDS Clinical Trials study sites and 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.	Begin work in Q1 (June 08); complete in Q2 (Nov 08)
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

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Data Management	DMC Harmonization Working Group	Harmonization of MedDRA coding	Consistent MedDRA coding of adverse events across studies and a higher MedDRA coding standard.	Ongoing
Data Management	DMC Harmonization Working Group	Identify issues and determine how data collection for transgender participants in DAIDS-funded HIV/AIDS clinical trials should be best conducted.	Improve data collections tools to better capture data on transgender participants while respecting their unique concerns.	TBD
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.	Begin work in Q2 (Sept 08)
Data Management	DMC Harmonization Working Group	Explore the role of the Office of Technology Information Systems (OTIS)	Formalize communication or coordination between the DMCs and OTIS.	Begin work in Q2 (Sept 08)
Evaluation	Evaluation Measurement Task Force	Work with 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

Infrastructure and Administrative Support

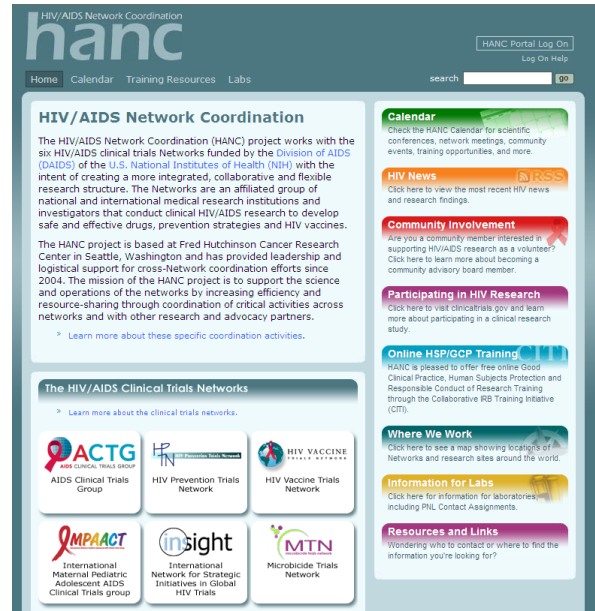
HANC Staff Role

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).

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.
- An HIV News section with the most recent HIV news and research findings.
- 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.



The HANC Portal

The HANC Portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. The HANC Portal includes document libraries; document development and version control management tools; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; and a cross-network directory linked to the DAIDS-ES Master Contact system. At the beginning of Year three, 396 individuals have active HANC Portal user accounts and twenty-three secure team sites are used by specific cross-network working groups for collective document development, online discussion, and sharing of materials and information. HANC Portal projects for 2008-2009 include:

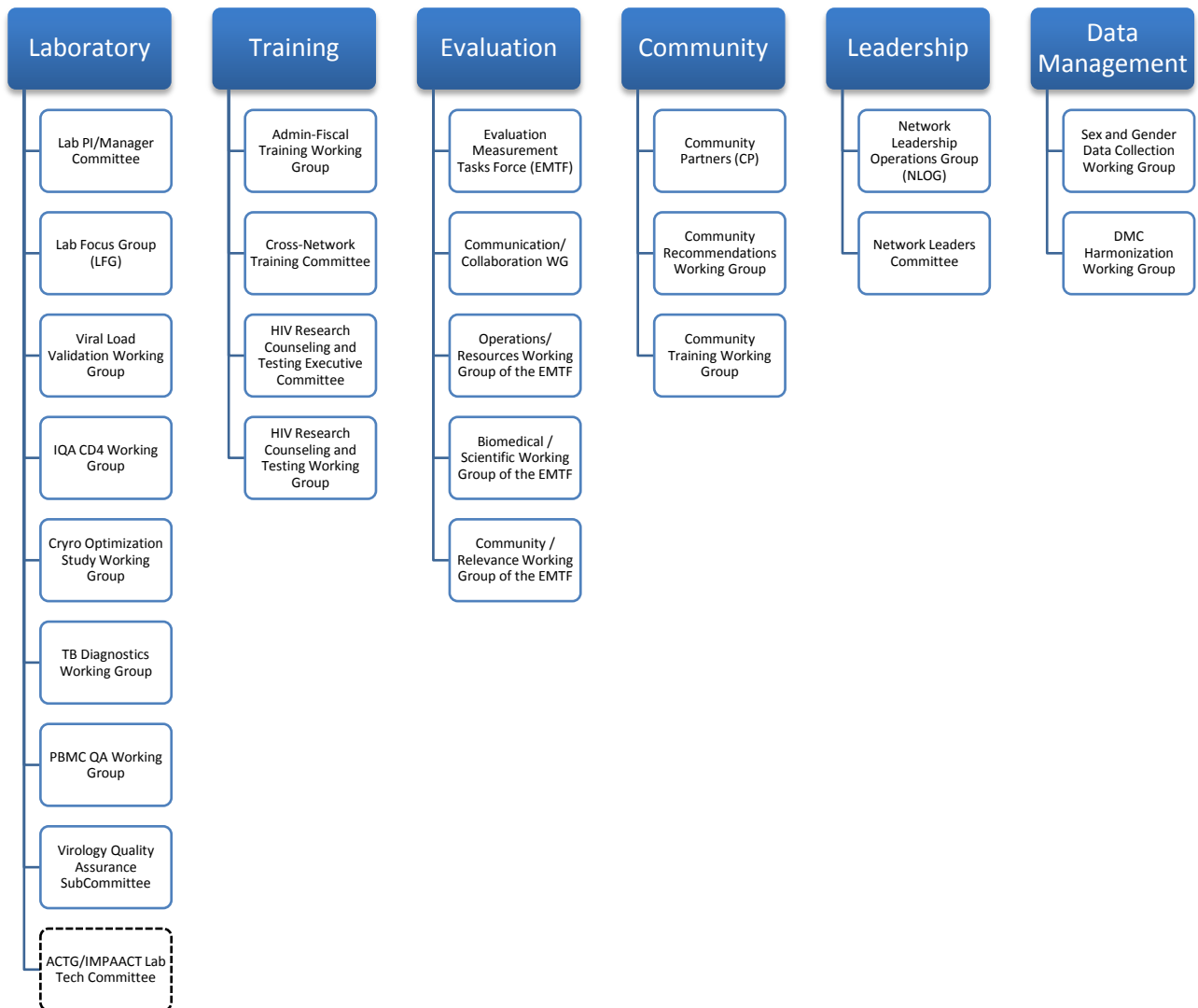
- Reviewing user statistics and member survey data collected in Q4 of Year 2 to inform redesigning the HANC Portal and improving team site content to better support the objectives of the project in Year 3.
- Maintaining web services that make the DAIDS-ES Master Contact system accessible to HANC Portal users.
- Support and optimization of the Proficiency Testing Performance Tracking tool which captures laboratory proficiency testing data and manages 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.

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, 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.

Committee and Working Group Coordination

Cross-network committees and working groups at the beginning of the June 2008–May 2009 time period include:



Objectives and Activities by Area of Coordination

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 calls include the participation of representatives from 18 NIH Institutes and Centers and provide a venue for cross-network as well as cross-institute information sharing and discussion. HANC solicits information from the Networks, NIH representatives and other partners to bring forward and organizes and facilitates every-other-month 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 NIAID-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 3-4 times a year to review and discuss scientific plans, progress and opportunities, specific protocols and cross-network issues. The HANC director participates in the SWG but the group is organized and facilitated by DAIDS.

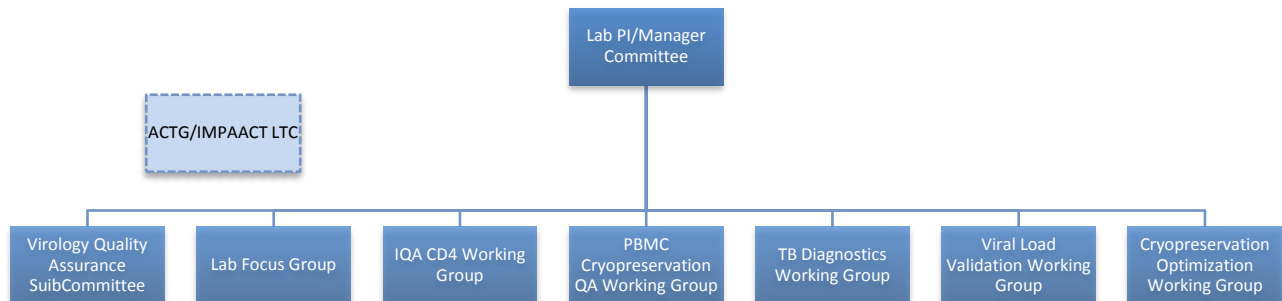
Network Leaders and DAIDS

HANC organizes focused monthly and ad hoc conference calls with the six Network Principal Investigators to address cross-cutting network leadership issues. HANC and DAIDS leadership also holds monthly conference calls to collaboratively identify and address issues and share updates on activities.

Laboratory Coordination Objectives and Activities

Laboratory Committees and Working Groups

HANC supports 6 active laboratory working groups and also provides technical support through a HANC Portal team site to the ACTG/IMPAACT Lab Tech Committee.



The Lab PI/Manager Committee includes Network Lab PIs, Lab Managers and DAIDS Clinical Laboratory Oversight Team (DCLOT) members who meet on monthly teleconferences to identify and address laboratory training, operations, and support issues that apply across Networks, and review progress and discuss issues raised by topic-specific working groups.

The Virology Quality Assurance Sub-Committee (VQASC) includes the Network Lab staff, Virology Quality assurance contractors, and DAIDS staff and addressed virology quality assurance proficiency testing.

The Lab Focus Group (LFG) includes the Network Lab staff and meets several times a month to do much of the detailed background, document development, and follow-up work to complete projects and tasks identified by the Lab PI/Manager Committee.

The Immunology Quality Assurance CD4 (IQA CD4) Working Group addresses CD4 proficiency testing issues identified by the IQA and UKNEQAS at international labs.

The PBMC Cryopreservation QA Working Group will be established to collaborate with the IQA in creating a robust cryopreservation external QA program.

The TB Diagnostics Working Group involves SMILE, CDC, IMPAACT and ACTG members to identify international site labs with capacity for TB laboratory diagnostic testing that could participate in trials with TB endpoints and/or become regional teaching centers, and pursue a more coordinated international approach to TB diagnostics and proficiency testing

The Viral Load Validation Working Group is a forum for the VQA to work with the networks to develop and implement a validation plan for viral load assays and come to consensus around a common process that will apply to all networks.

The Cryopreservation Optimization Working Group is designing a study for the Optimization of Storage and Transportation of Cryopreserved PBMC.

Laboratory Coordination Objectives for Year 3

Laboratory Coordination Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the Network Core Laboratory Programs.

Strategies and activities to support this objective:

- A face-to-face meeting will be scheduled as needed will bring together the Laboratory PIs, Laboratory Managers, DAIDS Laboratory program staff, and key contractors/partners.
- Monthly Cross-Network Laboratory PI/Manager Committee 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.
- Each working group has a team sites on the HANC Portal for information sharing and collaborative document development.
- The HANC public website “Information for Labs” 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 Core Laboratories until such time that they are captured in the DAIDS-ES system.

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 would improve the transparency and responsiveness of decision-making regarding results of proficiency testing at DAIDS-funded site laboratories by improving communication and timely access to relevant information.

Strategies and activities to support this objective:

- Review the TQM proposal developed and partially implemented in late 2006 and revise as necessary before taking the next steps toward full implementation. TQM program documentation will include general information about the overarching principles that guide TQM as well as the guidelines developed by the individual QA groups.
- Cross-network QA working groups will develop, review, and modify as needed guidelines for laboratory quality management including performance criteria and mechanisms for restricting protocol testing based on poor proficiency testing performance.
- Establish a PBMC Cryopreservation QA Working Group to collaborate with the IQA in creating a robust cryopreservation external QA program. This would include identifying elements to include in performance scoring (e.g. viability, timeliness, condition of specimens), a scheme for levels of performance (e.g. approved, provisionally approved, not approved), and consequences of poor performance. The PBMC Cryo QA WG would: develop an approach for IQA intervention/corrective action/remediation/training; formulate a communication scheme between the IQA and Network lab coordinators/leadership; review, in a blinded fashion, data about site performance in every round of EQA before performance status of sites is determined and notification is sent to sites; and serve as a forum to discuss complaints/disputes from sites.
- HANC Portal tools will continue to be utilized and modified when necessary to support review and tracking of proficiency testing results and associated corrective action 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.

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 making recommendations to the NLOG about how to implement changes to achieve these efficiencies.
- Identify where there would be value in developing consensus protocols for assays that are shared across the networks and do so.
- Implement the cross-network Viral Load Validation template and SOP developed in Year 2
- Collaborate as necessary with the DMCs to address LIMS-LDMS issues such as standardizing common data items used to identify specimens across networks.
- Identify which analytes used by the Networks require reference ranges and determine which of these reference ranges require local or regional definition; work with sites to ensure that where necessary local reference range studies are designed, funded and conducted.

Laboratory Coordination 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.

Strategies and activities to support this objective:

- Identify, evaluate and support TB laboratories that can serve as regional centers of excellence for:
 - Performing technically challenging TB testing in Network clinical studies
 - Conducting comparative evaluations of new TB diagnostic methods
 - Serving as regional training resources
- Be a resource to Network protocol teams for:
 - Maintain a list of international 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 of TB component of study-specific MOPs to include guidance on sample acquisition and processing prior to shipment to testing laboratories.

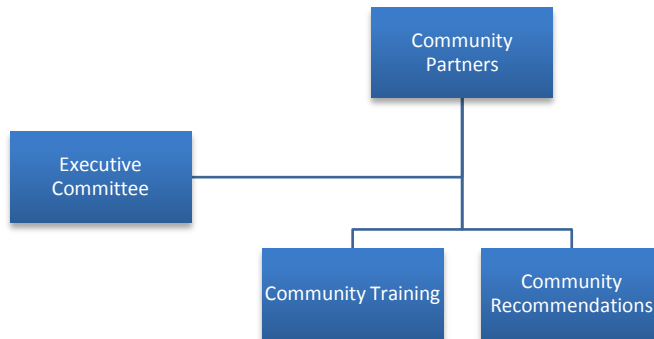
Laboratory Coordination Objective #5: Complete the PBMC QA study for optimization of a PBMC Cryopreservation Protocol, develop a PBMC Cryopreservation SOP based on the data generated, and work with a cross-Network working group to implement this SOP.

Community Coordination Objectives and Activities

Since the late 1990's, community representatives associated with DAIDS-funded research networks and studies have been working together to identify common issues and to learn new approaches and solutions from each relating to community involvement. A Cross-CAB Working Group (CCWG) was formed in 2003, and HANC began providing facilitation for their calls shortly afterwards. 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.

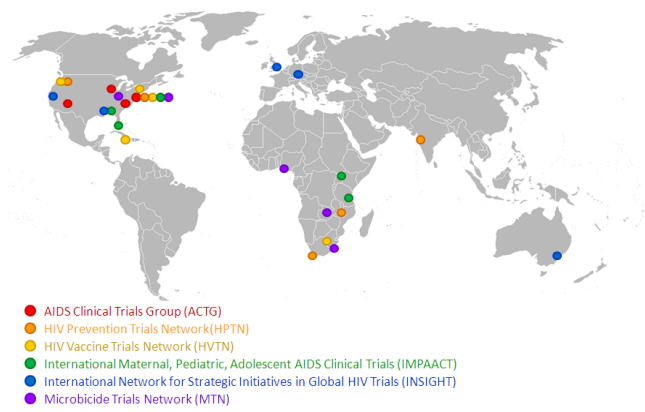
Community Partners and Working Groups

HANC supports Community Partners and any 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.

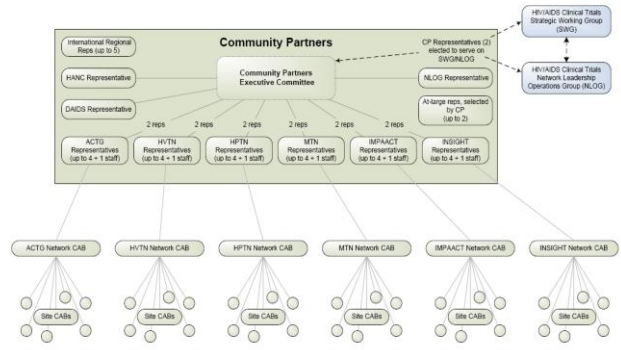


Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the DAIDS-sponsored HIV/AIDS Clinical Trials networks conduct research. CP represents cross-Network community research needs and priorities to network leadership and DAIDS 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.

Map of Community Partners Members' Locations - September 2007



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 Recommendations Working Group has developed specific recommendations for community involvement in DAIDS funded HIV Clinical Research Trials, based upon Best Practices document and community consultations.

Community Coordination Objectives for Year 3

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

Strategies and activities to support this objective:

- Identify Community Partners members willing 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: Finalization and dissemination of the recommendations on providing community input into the planning and implementation of research activities. The Community Recommendations working group completed most of the work in 2007-2008, and in 2008-2009 will be completing its activities before dissolving as a topic-specific working group.

Strategies and activities to support this objective:

- Finalize the “Recommendations for Community Involvement in NIAID HIV/AIDS Clinical Trials Research” including creating an executive summary.
- Create a distribution plan, taking into account the need to coordinate with and communicate differences between the Recommendations and the Good Participatory Practices that CP collaborated on which UNAIDS is currently field testing.
- Distribute recommendations document to network leadership and community groups.

Community Partners Objective #3: 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:

- The Community Training Working Group will select materials from the training library developed in Year 2 to make available as a resource on the HANC public website.
- The Community Training Working Group will seek partnerships with other groups that have training material for communities that addresses incorporating a human rights perspective into capacity building and participation in research.
- The Community Training Working Group will create simple training materials from existing content to give community members and network staff a better understanding of what Community Partners is and described the science and structure of the various.
- The Community Training Working Group will research and draft a proposal to contract with a technical writer to take existing training materials for a specific CAB training topic

(understanding the clinical research process) and compile them into a single standardized module that is relevant across the six DAIDS-funded HIV/AIDS clinical trials networks.

- If the proposal and use of CP funding are approved, a technical writer will be identified and the materials created for the CTWG as content experts to review and approve.
- The final module will be translated and distributed to relevant staff and community groups; the group may also provide train-the-trainer assistance.
- After completion of the first topic pilot; 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 #4: CP will consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate our progress and impact.

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.

Community Partners Objective #5: 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.

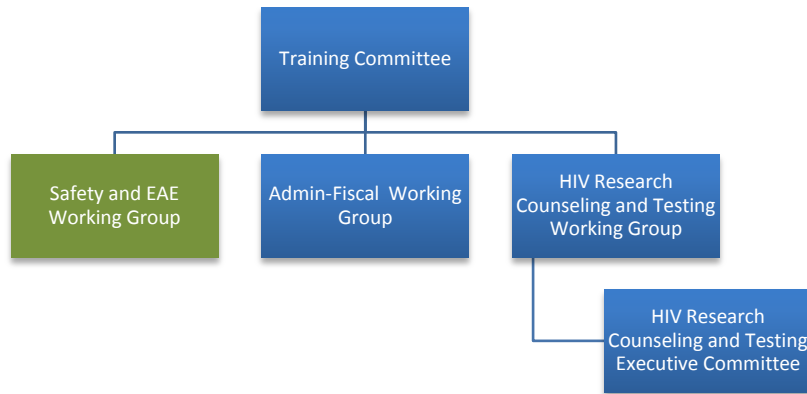
Strategies and activities to support this objective:

- Research the current site/CAB funding structure to better understand how the system works.
- Partner with the network leadership to assess how the site funding mechanism implemented in the new grant period has impacted community involvement at the network level, CTU level and CRS level.
- 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.

Training Coordination Objectives and Activities

Training Committees and Working Groups

HANC facilitates five cross-network training groups and provides technical support through a HANC portal team site for the developers of the Collaborative Institutional Training Initiative (CITI).



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 29 invitees/members from DAIDS, PAVE/DOD, PPD, FSTRF, Community Partners and each network.

The Admin-Fiscal Training Working Group was tasked with developing an administrative & fiscal training program for CTU staff to meet minimum NIH standards. In April 2007 Admin-Fiscal working group activity was placed on hold until the Office of International Extramural Activities (OIEA) completes their final training modules for the working group to compare with cross-network modules to avoid duplicating training development efforts. The working group is expected to reconvene in June 2008.

The Safety and EAE Working Group focuses on safety evaluation and reporting including broadened safety assessment training with a focus on EAE, attribution and case studies. In April of 2008, the working group changed to an ad hoc working group due to internal changes taking place within DAIDS to reformat their safety training program.

The HIV Research Counseling and Testing (HRCT) Working Group was convened when development of HIV Counseling and Testing was identified as a high priority topic area during the December 2006 Training Committee meeting. With HANC staff 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.

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 to check-in on the progress of the HRCT working group making sure the project stays on track and within budget.

Training Coordination Objectives for Year 3

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 will 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 which supports information sharing, lists training announcements, provides an area for training requests, contains a training documents library and allows for collaborative document development. Additional tools will be developed depending on the groups needs.
- Possible face-to-face working sessions may be held to bring together a specific working group or the training committee members, invitees and key contractors/partners.
- The HANC public website will provide CTU/CRS staff with information on upcoming training events and possible trainings available in electronic format.

Training Objective #2: Continue the development begun in year 2 of core training materials addressing risk reduction counseling in biomedical prevention and treatment trials.

Strategies and activities to support this objective:

- The HIV Research Counseling and Testing WG will meet on regular calls to develop and review the training curriculum.
- The HIV Research Counseling and Training Executive committee will meet on regular calls to ensure the project stays on track and within budget.
- HANC will coordinate ad hoc meetings between DAIDS, contractors and WG members in addressing different components of the curriculum.

Training Objective #3: Develop a modular administrative and fiscal training program.

Strategies and activities to support this objective:

- HANC will reconvene the Admin-Fiscal Training working group to review the grants management on-line trainings recently made available by the OIEA and identify gaps where additional admin-fiscal training development is needed. The Admin-Fiscal working group monthly calls will serve as a forum to address additional training needs.

Training Objective #4: Engage the networks and DAIDS in implementing a cross-network training program addressing issues of sustainability.

Strategies and activities to support this objective:

- HANC will work with DAIDS and the networks to identify ways to strategically address implementing a sustainable training program. Topics may include the formation of global learning communities, development of train the trainer or mentor programs and researching different options in funding available for training development and venues available for providing training, (i.e. webinars, network meetings etc.).
- Collecting and reviewing data from training needs assessments conducted by DAIDS and the networks to assist in identifying key training/capacity building needs.
- Continued review of evaluation data gathered from the DAIDS Regional Training Events.
- Monthly teleconferences with the Training Committee will serve as a forum for brainstorming different approaches.

Training Objective #5: Collaborate with the cross-network Lab PI/Manager Committee to provide access to on-line GCLP training once it is developed (See Laboratory Objective #3).

Training Objective #6: Collaborate with the cross-network DMC Harmonization working group and Community Partners to develop and provide training to site staff to better prepare them to be sensitive on transgender social and biomedical issues and interact more appropriately with transgender trial participants (See DMC Objective #5).

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 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 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.

Site Management and Logistics Coordination Objectives for Year 3

Site Management and Logistics Objective #1: In collaboration with relevant network staff, OPCRO and OCSO, develop a communication plan and process flow for how site management issues will be identified, addressed, and resolution communicated to all relevant stakeholders.

Strategies and activities to support this objective:

- Hold initial conversations with Network Leaders and OCSO that will clarify relative responsibilities of DAIDS and leadership groups for sites, identify how best for the networks to interface with OCSO and other groups at DAIDS, and inform the development of a communication plan and process flow.
- Develop and implement a site management issue communication plan and process flow.

Site Management and Logistics Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS offices 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. The list may include such issues as: reducing confusion around site monitoring by clarifying site performance monitoring; clarifying DAIDS and networks respective responsibilities and harmonizing site establishment processes to ensure that once approved sites are prepared to start new studies; insurance for clinical trials; site core budgets.
- Prioritize the list and convene topic-specific working groups on an ad-hoc basis to address and resolve particular issues.

Site Management and Logistics Objective #3: Partner with the National Institute of Mental Health (NIMH) to bring together the DAIDS-funded HIV/AIDS clinical trials networks and a few other partners to address critical cross-cutting issues in prevention adherence.

Strategies and activities to support this objective:

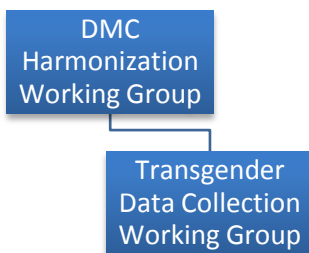
- HANC will coordinate a cross-network Steering Committee to assist NIMH in planning the agenda for the meeting.
- Hold a one and one-half day face-to-face meeting in Bethesda, Maryland in July 2008 with cross-network representatives to discuss (a) lessons learned from treatment adherence research; (b) state of the science adherence assessment; (c) improving adherence within clinical trials; and (d) accounting better for adherence effects on study endpoints and estimates of product efficacy. The goal is to explore lessons learned from treatment adherence and to apply them to HIV prevention in biomedical and other trials.

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 2 active data management related working groups.



The DMC Harmonization Working Group includes representatives from CHAVI, FSTRF, University of Minnesota and SCHARP, meets on monthly teleconferences, and carries out activities to address cross-network data management coordination objectives.

The Sex and Gender Data Collection Working Group includes representation from DMC or Core Operations center staff involved with data collection issues, Community Partners and/or other community members, and DAIDS staff. The working group is determining how data collection for transgender participants in DAIDS-funded HIV/AIDS clinical trials should be best conducted.

DMC Coordination Objectives for Year 3

DMC Coordination Objective #1: Implement Information Technology Best Practice Standards developed in Year 2 at DAIDS Clinical Trials study sites and affiliated laboratories and monitor infrastructure changes.

Strategies and activities to support this objective:

- The IT Best Practice standards document developed in Year 2 will be 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 will be done with monthly DMC Harmonization calls as a forum for discussing any proposed changes.

DMC Coordination Objective #2: Establish an “Input/Output transmission Standards” book that describes the necessary structure for data interchanges of assays, inventories, and manifests.

Strategies and activities to support this objective:

- Establish standards for clinical data formats associated with case report forms (CRFs).
- Establish standards for laboratory assay data formats associated with immunological and genomic sequences assays.
- Initiate discussions among the Networks surrounding Electronic Data Captures at sites and Data Management Centers.

DMC Coordination Objective #3: 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; and the DAIDS Repository (BBI/SeraCare) uses the DAIDS Repository BSI-II LIMS) were 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 the SCHARP Data Management Center 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 which can be read across multiple systems and reported back to SCHARP as part of an inventory data feed.

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 our studies. The SDMC 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:

- 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: Identify issues and determine how data collection for transgender participants in DAIDS-funded HIV/AIDS clinical trials should be best conducted.

Strategies and activities to support this objective:

- Work with the HVTN Transgender working group to identify issues around transgender participation in clinical trials, and further develop improved consensus data collection questions. Potential training needs may also be considered as part of this work.

DMC Coordination Objective #6: 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 #7: Explore the role of the Office of Technology Information Systems (OTIS) which manages technologies supporting NIAID biomedical research programs to establish an understanding of how they interact with the networks and sites and formalize communication or coordination with them.

Strategies and activities to support this objective:

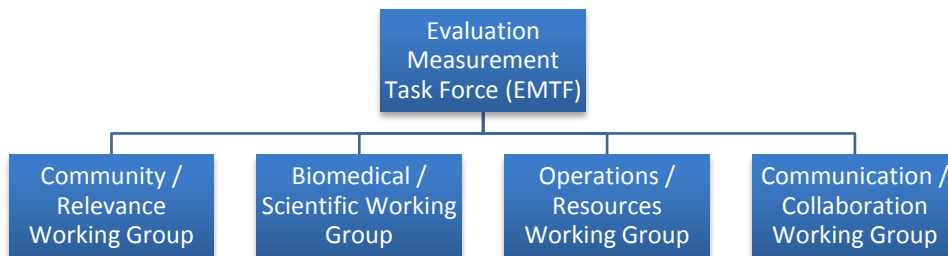
- HANC will establish a relationship with OTIS staff and invite them to present an overview of their activities to the DMC Harmonization working group.
- The DMC Harmonization working group will work with OTIS to identify opportunities for collaboration and ongoing information sharing.

Evaluation Coordination Objectives and Activities

The need for enhanced and harmonized network evaluation has been recognized among all the groups coordinating the management, operations, and scientific agendas of the networks. A Cross-Network Evaluation workgroup was established in December 2004 to address cross-network evaluation issues. In 2006 DAIDS, contracted with Concept Systems Incorporated (CSI) to develop an Evaluation System for DAIDS and its funded research programs. HANC has worked with DAIDS and CSI to collect and synthesize Network input for the DAIDS Network Evaluation Project, and involve the Networks and the cross-Network committees and working groups in the project. In 2008, an Evaluation Measurement Task Force will help in identifying evaluation questions that address each of the eight thematic categories of the evaluation framework and identifying potential ways of measuring progress.

Evaluation Committees and Working Groups

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



The Evaluation Measurement Task Force (EMTF) is a working group 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.

The Community/Relevance Working Group, the Biomedical/Scientific Working Group, the Operations/Resources Working Group, and the Communication/Collaboration Working Group are four working groups that each consist of network reps and HANC staff and focus on the specified areas of evaluation.

Evaluation Coordination Objectives for Year 3

Primary evaluation coordination objective for 2008-2009 include:

Evaluation 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.

Strategies and activities to support this objective:

- HANC to work with DAIDS, the networks and CSI in convening a F2F meeting in June to review each working groups work accomplished to date and identifying the next phase of work.
- HANC to hold monthly calls with each working group and CSI to progress the work of developing an evaluation system.
- HANC to participate in weekly calls with DAIDS and CSI as a way share the progress of each working group and provide feedback as necessary in regards to the overall project.

Activity Updates and Evaluating Coordination Progress

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

- Quarterly HANC progress reports posted on the HANC portal and sent to each Network Executive Committee; and
- An annual HANC progress report provided to NIAID Grants Management and posted on the HANC Portal.
- HANC staff are available to provide updates or presentations as requested.

The HANC office was created to address coordination needs identified by the Networks and DAIDS. As needs are addressed and new priorities or opportunities are identified, the potential impact of activities will need to be evaluated. In Year 3 HANC staff will continue developing quantitative and qualitative metrics to assess the impact of cross-network coordination activities. Implementation of these metrics will be done in conjunction with the EMTF, detailed in the Evaluation Coordination Objectives and Activities section.

As an office HANC is committed to seeking feedback from all of our partners on how we operate. HANC staff check-in on a regular basis with the individuals and the working groups they support; both informally and through formal mechanisms i.e. support surveys. The feedback shared informs changes in HANC staffing, processes and infrastructure.