HIV/AIDS Network Coordination
Year 4 Work Plan

June 1, 2009 – May 31, 2010

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, 2009 - May 31, 2010. 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 25.

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 collected in Q4 of Year 3 to inform HANC programmatic and portal improvements.	Improved 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.	Ongoing
Laboratory Coordination	Cryo Optimization Study Working Group	Complete study for optimization of PBMC Cryopreservation Protocol.	Optimized procedures for the Cryopreservation of PBMCs at Network-affiliated laboratories.	Completion target end Q4 (June 10)
Laboratory Coordination	ICAG	Develop IQA intervention, corrective action, remediation and training approach; formulate communication scheme.	Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories.	Completion target end Q4 (June 10)

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Laboratory Coordination	ICAG	Implement a plan for quality control of cryopreserved PBMC at the BRI repository.	Reliable results in functional and phenotypic assays.	Q1-Q2 (June-Nov 09) Finalize plan and begin pilot testing; Q3-Q4 (Dec 09-May 10) Revise plan and re-test
Laboratory Coordination	PBMC SOP WG	Implement Cross-Network PBMC SOP.	Consistent PBMC processing at network labs.	Q1 (July 09) Require PBMC SOP at all English-speaking network laboratories; Q2 (Nov 09) provide translated SOP and require use at all network laboratories
Laboratory Coordination	TB Diagnostics WG	Complete standard language for network protocols; complete site visits; implement standard guidelines for personnel safety	Safe and effective TB diagnostics for network protocols.	Q4 (Mar 10)
Community Coordination	Community Partners	Provide broad input and recommendations to DAIDS for upcoming Network recompetition and restructuring process.	DAIDS	Ongoing
Community Coordination	Community Partners	Gather 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	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.	Consultant has developed a DRAFT trainer's guide and training module on the topic of "understanding the clinical research process and principles of clinical research" for CAB members working with HIV clinical trial sites associated with the networks. Content experts and the CTWG will review and approve the draft materials. The final module will be translated and distributed to relevant staff and community groups. Ongoing
Community Coordination	Community Evaluation Working Group	Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact. Serve as advisory group to EMTF.	Clear measures to demonstrate the value of Community Partners. Data to identify opportunities to increase CP effectiveness.	Ongoing
Community Coordination	Community Site-Level Funding Working Group	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.	Q2
Training	Training Committee	Work with DAIDS and the network training representatives to create a training needs assessment (TNA). Form a subcommittee to review the TNA to prioritize training needs. Build-out the DLMS.	Provide training support to the sites.	Ongoing
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 09-Feb 10)

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Training	Admin-Fiscal Training working group	Develop a modular administrative and fiscal training program that supplements NIAIDs Grants Policy and Management Training.	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 Trial Logistics	Financial Disclosure Working Group	Develop a cross-network financial disclosure/conflict of interest SOP, synchronize reporting schedules, and implement a uniform web-based reporting system.	Eliminate redundant reporting requests and reduce the network's reporting costs.	Ongoing
Data Management	DMC Harmonization Working Group	Implement Information Technology Best Practice Standards 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.	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 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.	Ongoing
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 release policies across the networks.	Formalize expectations among network and DMC staff and reduce duplicative systems.	Ongoing
Data Management	DMC Harmonization Working Group	Establish mechanisms for data sharing between FSTRF and SCHARP.	Facilitate communication between DMCs, expedite data analysis for networks, and provide opportunity to share innovations.	

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
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

## 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 considering 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 task forces 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, such as 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.
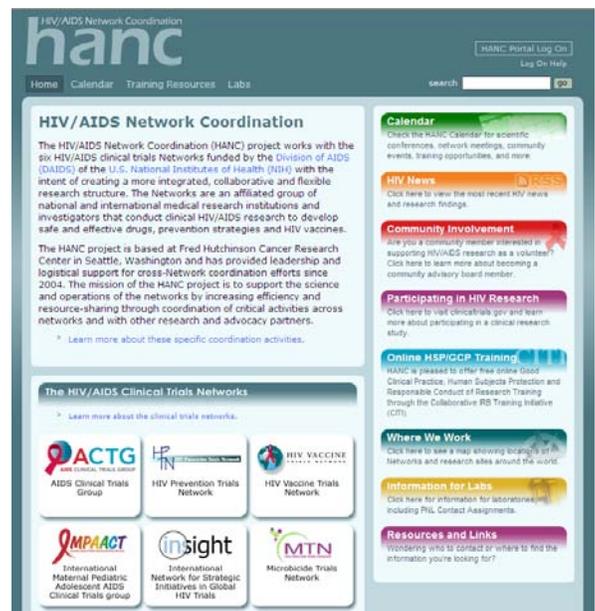
- Links to clinicaltrials.gov for individuals interested in participating in a clinical research study.

- 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.

- Year 4 will see the addition of a library of all the network publications cataloged in one central location for ready access on the HANC public website.

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 four, approximately 562 individuals have active HANC portal user accounts and thirty-eight secure team sites are used by specific cross-network working groups for collective document development, online discussion, and sharing of materials and information.
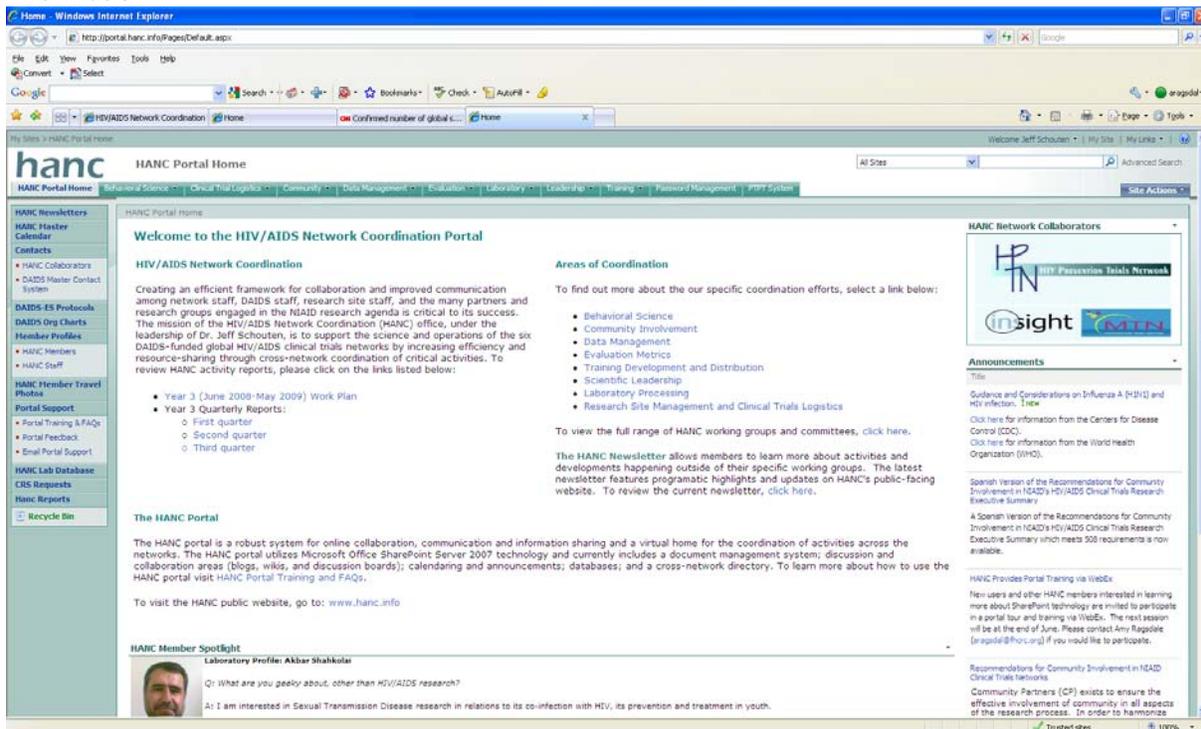
HANC Portal projects for 2009-2010 include:

- Reviewing user statistics and member survey data collected in Q4 of Year 3 to inform improvements to the HANC Portal and team site content to better support the objectives of the project in Year 4. Over 200 portal users responded to the HANC portal user survey conducted in Q4 of Year 3.

- 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 report data allowing ready access for all HANC portal users to this feature of the DAIDS-ES system.
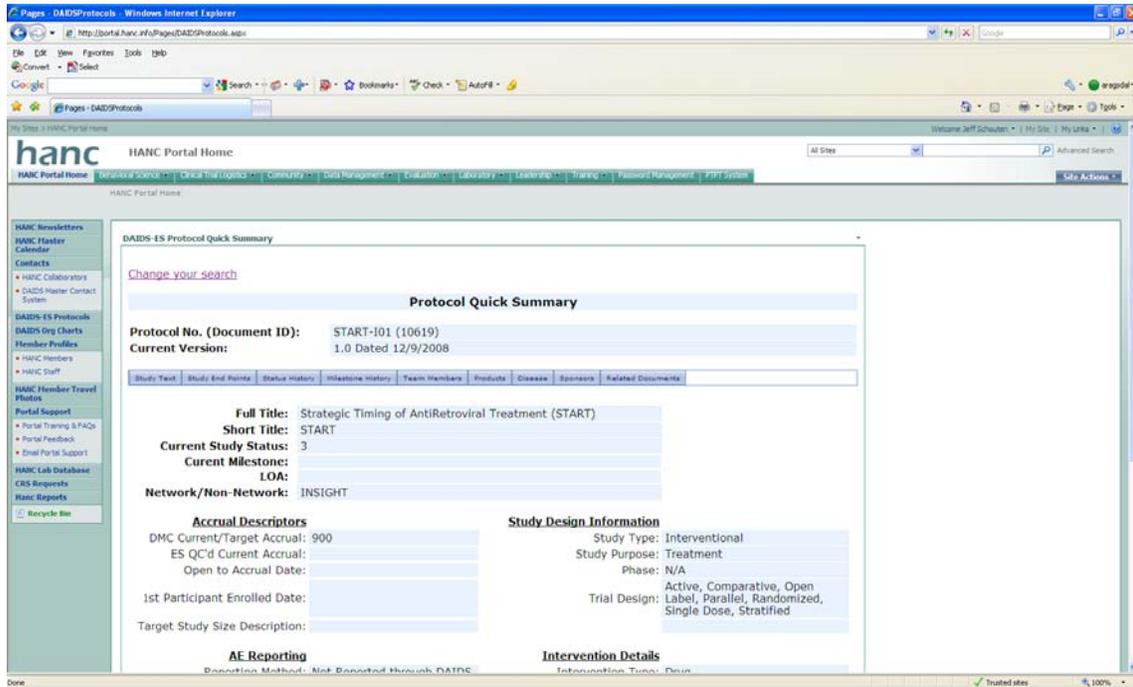
- Expansion of the lab data base to include equipment and platform inventories pending funding to support this activity.

- Continued 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.

- In Year 4 the new Behavioral Sciences Working Group will add a repository of adherence measures, data forms, and standardized core elements of interventions accessible to partnering networks to the HANC portal.

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.

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 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 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 by DAIDS to review and discuss scientific plans, progress and opportunities, specific protocols and cross-network issues. The HANC director participates in the SWG but the group is organized and facilitated by DAIDS.

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 hold monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC also holds a monthly call with the leadership of OCSO and a bimonthly call with the leadership of OSCO and OPCRO.

Behavioral Science Coordination Objectives and Activities

The Behavioral Science Working Group is a trans-NIH Institute and cross-network committee that was formed as an outcome of the July 2008 HANC and National Institute of Mental Health (NIMH) sponsored Prevention Adherence meeting.   The working group is charged with ensuring that the DAIDS clinical trials 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. HANC director Jeff Schouten participates on the monthly trans-NIH AIDS coordinator teleconferences.

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: Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings and workshops.

Laboratory Coordination Objectives and Activities

Laboratory Committees and Working Groups

HANC supports 12 active laboratory working groups and also provides technical support through a HANC portal team site to the ACTG/IMPAACT Lab Tech Committee (LTC).
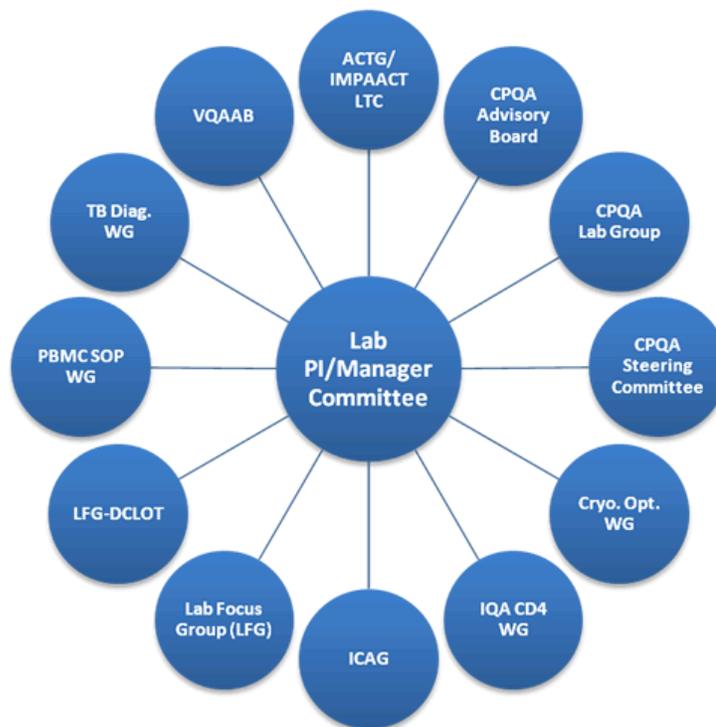
The Laboratory PI/Manager Committee includes Network Lab PIs, Lab Managers and DAIDS Clinical Laboratory Oversight Team (DCLOT) members, NICHD, data management center, and quality assurance contractors who meet on ad hoc teleconferences to serve as a central communication center for the other laboratory working groups and committees. The Lab PI/Manager Committee receives updates from the various laboratory working groups and discusses issues raised by them.

The 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 Cryopreservation Optimization Working Group is conducting a study for the Optimization of Storage and Transportation of Cryopreserved PBMC. The Cryo. Opt. WG includes representation from ACTG, IMPAACT, HVTN, CHAVI, DAIDS, SDAC, and the IQA.

The Immunology Quality Assurance (IQA) CD4 Working Group addresses CD4 proficiency testing issues identified by the IQA and UKNEQAS at international labs during monthly teleconferences. The IQA CD4 WG includes representatives of ACTG, IMPAACT, HPTN, HVTN, MTN, NICHD, DAIDS, SMILE 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 and quality control of cryopreserved PBMC samples at the Biomedical Research Institute (BRI) repository on monthly teleconference calls.

The Lab Focus Group (LFG) includes the network laboratory and operations staff and meets 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/DCLOT Group includes members of the LFG and DCLOT in order to facilitate communication on specific topics as needed. Calls are held on an ad hoc basis.

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 Diagnostics 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.

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/DCLOT teleconferences will facilitate communication among Network Laboratories and DCLOT 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 support staff will maintain a team site on the HANC portal for each working group for information sharing and collaborative document development.

- HANC support 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 DAIDS-funded 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, 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 and implement plan for quality control of cryopreserved PBMC at 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

- 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 support staff 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.

- Utilize the DAIDS Learning Management System (DLMS) to deliver and/or track laboratory training modules and manage training at the network and site levels.

- Implement the Cross-Network PBMC Processing SOP 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.

<u>Laboratory Coordination Objective #4:</u> 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, 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 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 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 diagnostics methods.

<u>Laboratory Coordination Objective #5:</u>

- Facilitate the completion the Cryopreservation Optimization Study, the objectives of which are to:

    □ Determine the length of time that cryopreserved PBMC can be safely stored at -70ºC before being shipped on dry ice and placed in liquid nitrogen at a repository.

   □ Determine the best shipment conditions for cryopreserved PBMC stored in liquid nitrogen.

- Facilitate the implementation the findings from the Cryopreservation Optimization Study as appropriate.

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.
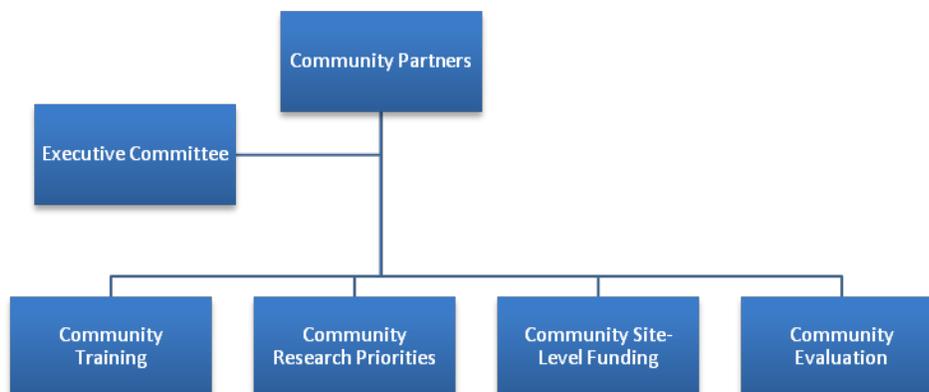

Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the DAIDS-sponsored HIV/AIDS Clinical Trials networks conduct research. CP represents cross-Network community research needs and priorities to network leadership and DAIDS 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- May 2009
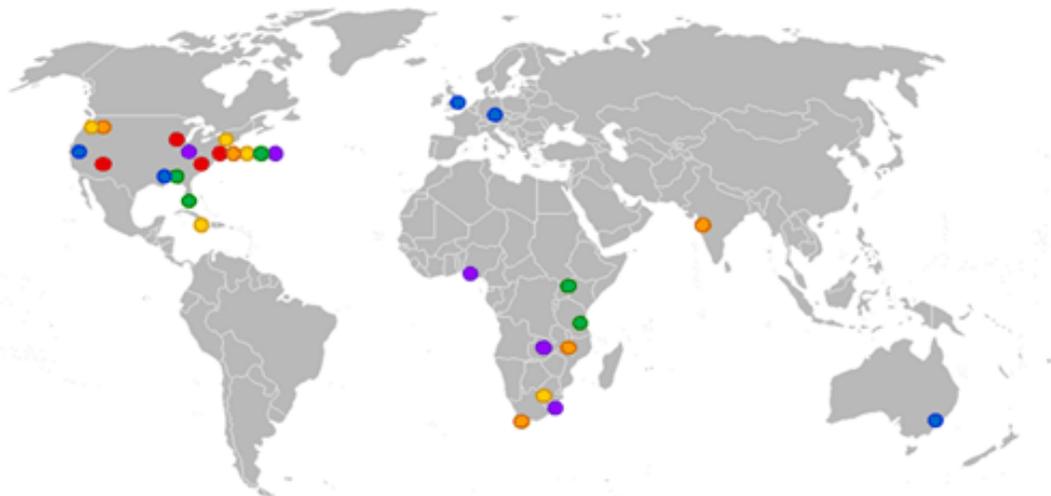
🔴 **AIDS Clinical Trials Group (ACTG)**
🟠 **HIV Prevention Trials Network(HPTN)**
🟡 **HIV Vaccine Trials Network (HVTN)**
🟢 **International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT)**
🔵 **International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)**
🟣 **Microbicide Trials Network (MTN)**

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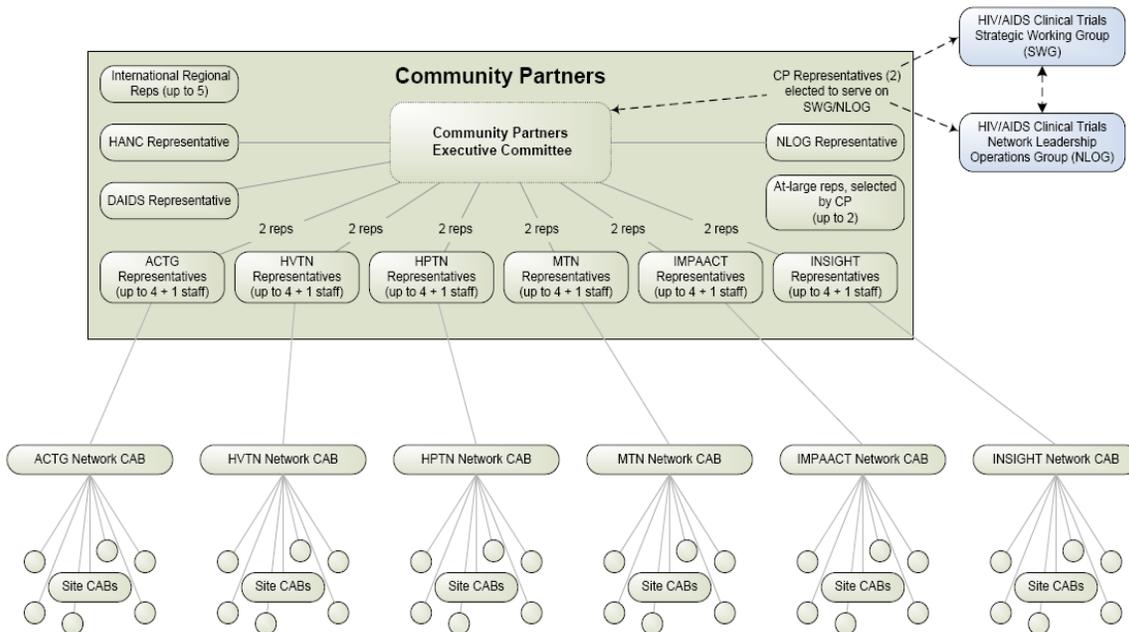
The Community Partners Executive Committee is drawn from the general membership of Community Partners and is empowered to make decisions on behalf of and in the best interests of CP and its general membership in accordance with CP Organizational Guidelines.

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 4

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:

- The technical writer will 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.

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- After the training materials content is reviewed and approved by content experts and the CTWG, 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 #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 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.

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, as well as external groups, regarding the recompetition and restructuring process and make recommendations that are actionable to DAIDS.

Community Partners Objective #6: Utilize CP to assist in gathering and collating information on community engagement mechanisms that are best practices across sites and share across networks.
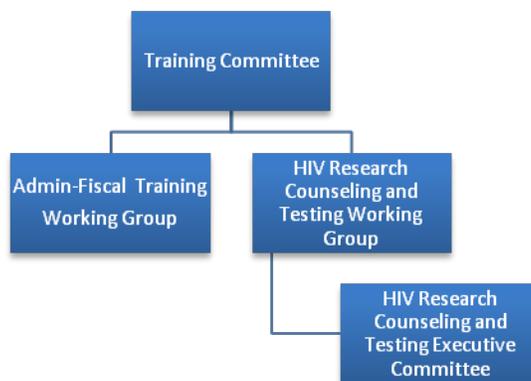
Strategies and activities to support this objective:

- 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.

Training Coordination Objectives and Activities

Training Committees and Working Groups

HANC facilitates four 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 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 Training 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 Fall 2009.

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 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 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, training topics blog and allows for collaborative document development. Additional tools will be developed depending on the groups needs.

- The HANC public website will provide CTU/CRS staff with information on upcoming training events and training resources available in various formats.

- HANC will work with DAIDS and the networks to create a cross-network training needs assessment. A subcommittee to be formed to review the template and prioritize the training needs once information is collected.

- Work with DAIDS and the networks to build-out the DAIDS Learning Management System as a useful tool to host available training and serve as a tracking mechanism for trainees.

- Continued review of evaluation data gathered from the DAIDS Regional Training Events.

- Engage the networks and DAIDS to review different processes in order to implement long term training support to the sites both operationally and financially.

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 that supplements NIAIDs Grants Policy and Management Training.

Strategies and activities to support this objective:

- HANC will work with DAIDS, the CRS team and reconvene the Admin-Fiscal Training working group as necessary, 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.

Training Objective #4: 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 #3).

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 4

Site Management and Logistics Objective #1: Work closely with network staff and DAIDS officers to harmonize network Conflict of Interest/Financial Disclosure requirements, synchronize network financial disclosure reporting schedules, and develop a cross-network web-based reporting interface, pending availability of funds for the latter effort.

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 new performance monitoring policies; clarifying DAIDS and networks respective responsibilities and harmonizing site establishment processes;; and address issues relevant to 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: Investigate the feasibility of the establishment of a centralized IRB review process for network protocols. HANC will study the experience of the HVTN in establishing a central IRB at the Fred Hutchinson Cancer Research Center for HVTN's 505 protocol. Building on that experience HANC will determine if there is interest among the other networks in trying to establish a centralized IRB. This subject will be discussed on the first NLOG call of Year 4.

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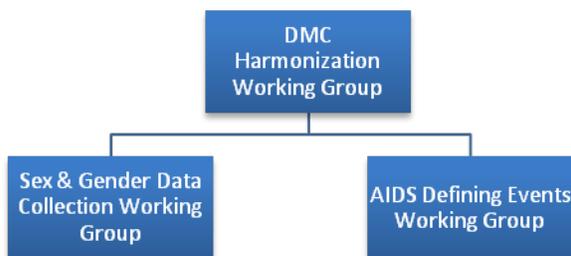
The DMC Harmonization Working Group includes representatives from CHAVI, FSTRF, University of Minnesota and SCHARP, meets on monthly teleconferences, and carries out activities to address cross-network data management coordination objectives.

AIDS Defining Events Working Group includes representatives from SCHARP, SDAC, and FSTRF 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.

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 4

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

Strategies and activities to support this objective:

- The IT Best Practice standards document developed in Year 3 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.

- Continue the dialogue with OTIS to establish understanding of how the organization will work with the networks.

<u>DMC Coordination Objective #2</u>: 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.

<u>DMC Coordination Objective #3</u>: 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.

<u>DMC Coordination Objective #4</u>: 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.

<u>DMC Coordination Objective #5</u>: 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:

• 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 #6: Harmonize data release policies across the networks.

Each of the networks has different rules regarding data release. The DMC will endeavor to standardize the policies and procedures across network and the statistical and data management centers.

Strategies and activities to support this objective:

● In consultation with DAIDS and network operation centers, SCHARP, SDAC and FSTRF will determine to whom, when, and how data should be released.
● The group will draft a recommendations document to be circulated to DAIDS and Network Leadership for approval.

DMC Coordination Objective #7: 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 request to DAIDS as well as report back these experiences to the full DMC working group as needed.

DMC Coordination Objective #8: Develop a "DAIDS Contacts FAQ" for data management-related issues.

SCHARP and FSTRF have expressed interest in having a DAIDS contacts reference guide for questions pertaining to data and grants management.

Strategies and activities to support this objective:

● Work with DAIDS staff to compile a list of relevant DAIDS employees and contractors and post to the HANC portal. The list will be updated as necessary.

DMC Coordination Objective #9: 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 #10: 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 DIADS staff regarding the development and requirements of the (DAERS).

- Share experiences interfacing with the DAERS system on monthly DMC conference calls.

DMC Coordination Objective #11: Establish mechanisms for data sharing between FSTRF and SCHARP.

Strategies and activities to support this objective:

- Research and develop online tools to expedite cross-DMC data sharing.

- SCHARP and FSTRF will hold ad hoc conference calls to share programming ideas, discuss newly available technologies, and demonstrate how the programs are used.

- HANC will host ad hoc conference calls to facilitate the collaborative endeavor.

Evaluation Coordination Objectives and Activities

The Division of AIDS (DAIDS) began the implementation of an evaluation system for DAIDS and its HIV/AIDS clinical research networks in Year 3. Federal statutory and NIH mandates require DAIDS to conduct evaluations of its operations and programs. 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, and 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.
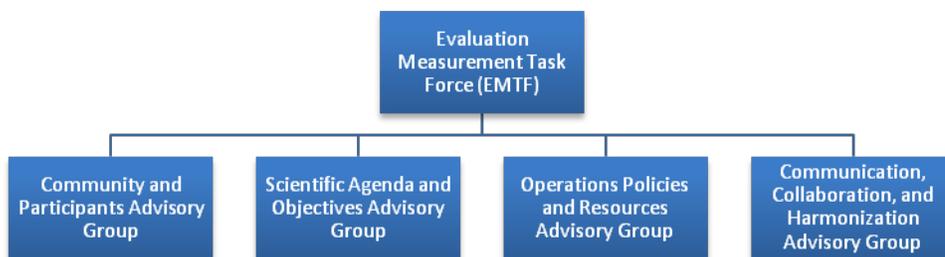
The Evaluation Measurement Task Force (EMTF) is comprised of representatives from each of the networks, DAIDS and HANC. The task force will provide detailed, technical input about potential measures, data sources and tools to be considered for use in the development of the evaluation system plan.

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 the HANC office; and 4) the coordination and maximization of research opportunities.

Evaluation Coordination Objectives for Year 4

Primary evaluation coordination objective for 2009-2010 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 biweekly 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.

HANC Activity Updates

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.

- An annual HANC progress report provided to NIAID Grants Management and posted on the HANC portal.

- HANC to produce quarterly newsletters distributed to all portal users and posted on the home page of the HANC portal.

- HANC to distribute an annual survey to all of HANC's collaborators which will evaluate 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 any other meetings.