

Infrastructure and Administrative Support

The HANC Public Website

The HANC public website (www.hanc.info) provides information and resources for collaborators, research sites, and the general public. Functionality and content added to the website this quarter included:

- OCSO SOPs
- Pages for the DAIDS ES Applications



Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
HANC staff	Review design and flow of the HANC website and reorganize to improve functionality and ease of use.	Improved communication and access to information.	Q2-Q3	Updated Training Resources page and created "About HANC" page. Added "Contact Us" links to encourage engagement with website users. Dedicated web pages to access detailed information for DAIDS ES applications which includes DAERS, CSM and Protocol Registration.

The HANC Portal

The HANC Portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. During this quarter we had a net gain of 137 individuals with HANC portal user accounts, for a total of 733 active HANC Portal user accounts. Four additional team sites were developed this quarter, including the new Behavioral Science F2F Steering Committee, the Legacy Project Advisory Group, Legacy Project Working Group, and the ACTG-IMPACT Laboratory Technician Committee Workload Tracking for a total of 44 team sites. HANC portal projects for 2009-2010 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
HANC staff	Review user statistics and member survey data collected to inform HANC portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives.	Ongoing.	Google Analytics have been installed on the HANC public web site and monthly usage reports from the HANC portal and team sites are being generated.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
HANC staff	Provision of the DAIDS-ES protocol reports on the HANC portal.	Ready access to all protocol reports including the quick summary data and accrual data from the DAIDS-ES system in real-time for HANC portal users.	Development completed.	Ongoing activities include embedding links to protocol reports in call minutes, linking to protocols referenced in the HANC newsletter, and updating the protocol report details as necessary.
HANC staff	Feasibility of linking to the DAIDS-ES document library of all approved network protocols on the HANC portal.	Ready access to all network approved protocol documents for HANC portal users.	Q4.	HANC received approval to link the DAIDS-ES document library to the protocol reports available through the HANC portal-DAIDS-ES web feed. Service will be initiated in next DAIDS-ES upgrade in April 2010.
HANC staff	Adding features and resources for HANC members.	Improved resource and information sharing amongst HANC members.	Ongoing.	Expanded the member profile library, reorganized the portal homepage, and added a "Portal Tips" web part.
HANC and IST staff	Created two new order forms and order management systems for Virology Quality Assurance (VQA).	Expand the number items the VQA can offer to its customers and improve order management efficiency.	Q2 Development new order forms; Q3 Complete form libraries and launch.	Completed new order forms and form libraries; initiated testing.

Social Networking & Information Sharing

HANC has established Twitter (search for "Hancprograms") and Facebook (search for "Hanc Programs") accounts to share general programmatic updates with a broader audience. Due to the interest in the resources shared in the HANC newsletter, HANC staff has increased the publication frequency from quarterly to bi-monthly. "HANC Portal 101s" are now offered on a bi-monthly basis. HANC members are invited by HANC to participate in a walk-through of portal/website resources and given the opportunity to learn more about SharePoint technology.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held 1 call this quarter during which major network protocols in development were reviewed and H1N1 influenza protocols in development were discussed. Russell Campbell and Allegra Cermak provided background on the documents and presented to the group new materials developed by the Community Partners Training Working Group (CTWG) which include a cross-network trainer's guide, participant's guide and training module on the topics of "Understanding The Clinical Research Process And Principles Of Clinical Research" and "The Role Of A CAB And Principles Of Community Involvement". HANC organized 3 focused monthly conference calls with the six Network Principal Investigators to address cross-cutting network leadership issues. HANC and

DAIDS leadership also held monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC held monthly calls with OCSO leadership and two calls with OCSO and OPCRO leadership during which OPCRO presented their Protocol Risk Assessment Project and OSCO discussed their new site monitoring plan. HANC collated comments for OPCRO on the draft of the “Manual for Expedited Reporting of Adverse Events (EAEs) to DAIDS”, version 2.0. HANC also worked with OCSO and disseminated information about the site infrastructure awards. HANC continued to work with OPCRO and the networks and disseminated information about the new ClinicalTrials.gov results reporting requirements.

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.				
ACTG/IMPAACT LTC and HANC Support Staff	Develop and maintain a Lab Tech (LT) Committee Workload Tracking System.	Track information about LT work assignments to ensure equitable sharing of responsibilities.	Q2 Develop and launch; Q3 Expand reporting capabilities; maintain throughout the year.	LT Workload Tracking System developed and launched.
ACTG/IMPAACT LTC and HANC Support Staff	Develop and launch a Lab Processing Chart (LPC) Resource Library on the LTC team site.	Provide a space to collect resource documents for the development and review of LPCs	Q2 Develop and launch.	LPC Resource Library developed and launched.
Lab PI/Manager Committee	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion and updates from the laboratory working groups.	Ongoing throughout the year.	<ul style="list-style-type: none"> • Distributed two sets of working group updates to the committee. • Held one conference call to review first year of CPQA program and FDA-approval for IND studies.
Lab Focus Group/LFG-DCLOT Collaborative Working Group	Develop communication plan for laboratory audits.	Define a clear and consistent communication plan among Network Laboratories, DAIDS and SMILE for timely resolution of audit findings.	Q1 Incorporate feedback from DAIDS; Q2 Incorporate feedback from SMILE and finalize plan.	Incorporated feedback from SMILE and finalized plan.
Lab Focus Group/LFG-DCLOT Collaborative Working Group	Determine process for vetting new labs.	Minimize unnecessary additions of new labs to DAIDS system, thereby minimizing resources necessary for lab start-up and monitoring.	Q2 Collect information; Q3 determine process.	Q2 Collected information about the nature of new lab requests from SMILE, DAIDS and networks; initiated discussions.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Lab Focus Group	Review and revise Primary Network Laboratory Assignments; distribute updates to quality assurance providers.	Streamline communications regarding proficiency testing failure, audit reports and action plans.	Q2 Review, revise and distribute updates.	Completed.
Lab Focus Group	Extend membership to include Westat personnel who oversee NICHD-funded IMPAACT labs.	Streamline communications and decision making regarding laboratory activities.	Q2 Add Westat members to Lab Focus group.	Completed.
LFG-DCLOT Collaborative Working Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for discussion among Network Laboratories and the DAIDS Clinical Oversight Team.	Ongoing.	Held two conference calls, during which the group: <ul style="list-style-type: none"> • Finalized lab audit report communication plan • Discussed requirements for FDA-approved reagents for IND studies • Discussed back-up plans for all labs • Resolved how to best treat analytical study plans in audit shell.
HANC Support Staff	Redesign Laboratory Coordination and Laboratory Resources portions of the HANC public website.	Provide clear information to the general public and laboratories about the working groups and their roles and make various resources available to labs.	Ongoing.	Regularly updated page about ordering fetal bovine serum.
HANC Support Staff	Develop and maintain a HANC Laboratory Database for network-affiliated international labs.	Provide a common resource for the storage and maintenance of laboratory information; develop consensus laboratory names to ease communications among network laboratory staff and contractor staff.	Ongoing.	Updated laboratory contact information using monthly PPD updates, and miscellaneous notifications from labs.
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.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Lab Focus Group	Review and modify the Safety Lab Quality Assurance Guidelines to reflect current practices and goals for publication on the HANC public website.	Clarify and outline responsibilities, monitoring, data and communication flow within the Safety EQA program as part of the TQM document.	Q1 Send to DAIDS and SMILE for approval; Q2 finalize and post on public website.	On hold in favor of more urgent issues.
Lab Focus Group	Develop guidelines for back-up plans for safety labs.	Consistent quality control of safety testing at Network-affiliated laboratories and back-up labs.	Q1 Draft plan, review within LFG and send to SMILE and DAIDS for review; Q2 incorporate feedback from SMILE and DAIDS; Q3 finalize plan.	Incorporated feedback from SMILE and DAIDS.
Lab Focus Group	Establish oversight of U.S. CD4 laboratories.	Ensure standard quality assurance for CD4 testing in the U.S. for network protocols.	Q2 Collect information about how U.S. CD4 laboratories are currently overseen by the networks; Q3 Collect information about IQA CD4 program in the U.S.; Q4 Establish mechanisms for network oversight of U.S. CD4 proficiency testing results and incorporate into TQM.	<ul style="list-style-type: none"> Collected information about how U.S. CD4 laboratories are currently overseen by the networks Requested overview presentation of IQA CD4 program.
IQA CD4 Working Group	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA CD4 labs.	Consistent quality control of IQA CD4 testing at Network-affiliated laboratories.	Ongoing.	<p>Held three calls during which:</p> <ul style="list-style-type: none"> Testing issues at labs were discussed and resolved. Development of back-up plans for CD4 Labs was continued. Effectiveness of tracking and communication tools was reviewed.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
IQA Cryopreservation Proficiency Testing Advisory Group (ICAG)	Develop IQA intervention, corrective action, remediation and training approach; formulate communication scheme and document as part of the TQM document.	Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories.	Completion target Q4 (May 10).	Held three calls, during which program criteria were completed.
ICAG	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA PBMC labs.	Consistent quality control of IQA PBMC cryopreservation testing at Network-affiliated laboratories.	Ongoing throughout the year.	Two specific proficiency testing issues were resolved.
ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository.	Reliable results in functional and phenotypic assays.	Q1 Develop algorithm for selecting samples at BRI for QC; Q2 initiate pilot testing of incoming samples and testing of samples at BRI.	<ul style="list-style-type: none"> Discussed various options for quality control cryopreserved samples at the BRI repository. Initiated pilot testing of incoming samples.
ICAG	Develop ICAG Working Group Guidelines to reflect current practices and goals for publication on the HANC public website.	Clarify and outline responsibilities, monitoring, data and communication flow within the IQA PBMC Cryo PT program as part of the TQM document.	Q3 and 4 finalize and post	Guidelines were drafted and then put on hold in favor of more urgent issues.
CPQA working groups (Advisory Board, Steering Committee and Lab Group)	Maintain a structure, processes and a forum for consistent communication about the CPQA PT program and labs.	Consistent quality control of pharmacology testing at Network-affiliated laboratories.	Ongoing throughout the year.	<p>Held 6 calls during which the CPQA working groups communicated program details to relevant parties and reviewed:</p> <ul style="list-style-type: none"> AVR SOP Review Process CPQA Program By-Laws Training options and plans Changes to the CPQA website and LDMS.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Virology Quality Assurance Advisory Board (VQAAB)	Maintain a structure, processes and a forum for consistent communication about and performance review of VQA labs.	Consistent quality control of virology testing at network-affiliated laboratories.	Ongoing throughout the year.	Held 3 monthly calls during which the group reviewed proficiency testing reports and cumulative performance summaries and discussed: <ul style="list-style-type: none"> • Specimen processing time limits • Controls for new viral load platforms • DNA PCR dried blood spot analyses.
Objective #3: Identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.				
ACTG IMPAACT/LTC and HANC Support Staff	Update Lab Process Chart (LPC) standard wording and format.	Improve design of LPC for efficiency and user-friendliness and update standard wording to reflect current practice.	Q1 Divide LPC into sections and assign primary editors to each section; Q2 initiate updates to standard wording; Q3 complete updates to standard wording; Q4 reformat LPC.	Initiated revisions to standard wording.
ACTG IMPAACT/LTC and HANC Support Staff	Add comments and example reference documents to PBMC Lab Audit Shell.	Provide laboratories with guidelines for audit readiness.	Q1 Divide shell into sections and assign primary editors to each section; Q2 compile comments and resources; Q3 finalize.	Compiled revised sections of audit shell and resources.
Lab Focus Group	Provided estimates of needed Roche kits to Roche.	Ensure adequate supplied of kits for network protocols that would otherwise be discontinued.	Q2 Determine Roche requirements; Q3 complete estimates	Initiated determination of Roche requirements.
Lab Focus Group	Recommend and implement new real-time viral load assay for use in network protocols with viral load primary endpoints.	Reliable and consistent data collection.	Q1 Supervise installation of instruments at priority sites; Q2 complete installation.	Held 2 calls with Abbott to review status of implementation and provide information and guidance; status of installation pending.
TB Diagnostics WG	Develop guidelines for sputum samples collection and transport.	Provide guidance for development of protocols with TB endpoints.	Q1 Draft; Q2 finalize and distribute to ACTG/IMPAACT LTC.	Finalized and distributed to LTC.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
PBMC SOP Implementation Working Group	Develop and implement a cross-network/CHAVI PBMC Processing SOP.	Consistent PBMC processing at network and CHAVI labs.	Q1 Revise SOP, post version 2 on HANC public website, translate SOP into Spanish, French, Portuguese and Thai; Q4 review/revise PBMC SOP based on new information and feedback.	Thai translation posted. All translations are complete.
Objective #4: Continue collaborating amongst the Networks, HANC, DAIDS and SMILE to improve TB diagnostics, TB proficiency testing and participation of labs with TB diagnostic capacity in Network protocols where TB is a component.				
TB Diagnostics Working Group	Plan site visits to TB diagnostics labs.	Evaluate TB diagnostics labs for capacity to participate in network protocols and serve as regional training centers.	Ongoing.	<ul style="list-style-type: none"> Reviewed site visits reports from three labs in South Africa and Botswana for July, 2009. Planned site visit in Thailand for January 2010. Held one call to review TB lab protocol readiness.
TB Diagnostics Working Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for communication among the networks, SMILE and DAIDS regarding TB laboratories and diagnostics.	Ongoing.	<p>Held two calls to review:</p> <ul style="list-style-type: none"> Site visit reports and plans PPD audit shell for TB/AFB labs Site EQA status Guidelines for specimen storage and transport Use and validation of Microbank tubes for sample storage Upcoming TB protocols Point-of-Care TB diagnostics technology.
TB Diagnostics Working Group	Develop draft language for network protocols that use TB diagnostics.	Provide standard language for networks to use in protocols that use TB diagnostics.	On hold in Year 4.	This project is on hold.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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.				
Cryo Optimization Study Working Group	Complete study for optimization of PBMC Cryopreservation Protocol, develop a new standard SOP based on data generated, and implement the SOP.	Consistent optimized procedures for the cryopreservation of PBMCs at network-affiliated laboratories.	Completion target end Q2 (December 09).	<ul style="list-style-type: none"> Held three calls to review data and analyses. Group Chair presented findings at ACTG/IMPAACT Leadership Retreat. <p>This project is complete.</p>

Behavioral Science Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science.				
Behavioral Science Working Group	Propose behavioral science plenary sessions to network conference planning committees. Curate and organize sessions.	Identify network and behavioral science agendas/priorities and identify gaps, overlaps and provide input from the behavioral science perspective in shaping agenda items.	Ongoing.	Helped coordinate the “Behavioral and Social Science in HIV Vaccine Clinical Research: Workshop Report” breakout session at the November 2009 HVTN conference. HANC director, Jeff Schouten, presented on HANC’s role supporting cross-network/trans-Institute behavioral and social science research. The BSWG will continue to propose topics for network meetings.
Objective #2: Create a repository of behavioral science tools and measures.				
Behavioral Science Working Group, NIMH	Create a library on the HANC portal for all BSWG members to access “state of the science” measures, forms, and articles.	Allow investigators to compare efficacy of research tools and share outcomes of behavioral science substudies/practices in network clinical trials.	Ongoing	The library has been created and is updated as able.
Objective #3: Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings and workshops.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Behavioral Science Working Group, NIMH	Provide opportunity for investigators to share ideas and collaborate on behavioral science materials and recommendations.	Ensure that the best quality behavioral science is integrated into clinical trials	Ongoing.	Discussed developing a white paper on prevention adherence in HIV clinical trials with the Forum for Collaborative HIV Research.
Objective #4: 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.				
HANC, F2F Steering Committee	Coordinate a cross-network Steering Committee to assist NIMH in planning the agenda for the meeting. Hold a face-to-face meeting with cross-network representatives.	Explore HIV/AIDS related behavioral science research and apply them to network clinical trials.	Q4.	Formed a meeting steering committee, discussed possible meeting topics, researched hotels.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Develop a community research priorities agenda.				
Community Partners Research Priorities Working Group	Draft a clear written outline of the project scope, intent, timeline and criteria to determine project success. Identify CP members to work on this project. Develop the research agenda.	Identify network and community scientific agendas/priorities and identify gaps, overlaps and provide input from the community perspective into the research agenda.	Q4, target completion, perhaps beyond.	The group held three conference calls and compiled a list of the various network research priorities and examined the list to determine what category or categories would fit a particular priority. Based on that compilation, the Working Group developed a spreadsheet displaying the various research categories. The group is working on the best format to display the priorities and highlight overlaps and gaps in the networks' research agendas.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #2: Utilize the Community Training Working Group to share existing CAB training materials, identify and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules.				
Community Training Working Group	<p>Post materials from the training library on the HANC public website.</p> <p>Partner with groups to incorporate a human rights perspective into capacity building and research participation.</p> <p>Create simple training materials from existing content describing Community Partners as well as the science and structure of the networks.</p> <p>Draft proposal for contract technical writer to compile materials for “Understanding the clinical research process” into a single standardized module relevant across networks.</p>	<p>Common CAB member understanding of basic concepts in HIV disease, clinical trials methodology, and CAB role.</p> <p>Improved training quality and consistency.</p>	Q4, target completion, perhaps beyond.	<p>Finalized and distributed a cross-network trainer’s guide and training module on the topics of “Understanding the clinical research process and principles of clinical research” and “The role of a CAB and principles of community involvement”. Presented the training materials to the Cross-Network Training Committee to determine if the networks are interested in offering the training during full group meetings and whether this training would be beneficial to add to DRTEs or build-outs are web modules. Also presented the materials developed to the NLOG on their November call.</p>
Objective #3: Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact and serve as an advisory group to the EMTF.				
Community Partners Evaluation Working Group	<p>Develop a continuous quality improvement process for CP.</p> <p>Identify objective metrics and mechanisms for evaluating the impact of CP activities.</p>	<p>Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.</p>	Ongoing.	<p>In addition to holding three conference calls the group held a joint conference call with the Site-Level Funding work group to revise survey questions and collaborate with that working group to be more effective. The group will update the EMTF on their progress.</p>
Objective #4: Review site-level CAB funding and support in the current grant period to identify areas where funding and support mechanisms are working well and areas where there are problems or opportunities for improvement.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Community Partners Site-Level Funding Working Group	<p>Research current site/CAB funding structure to understand the system.</p> <p>Partner with the network leadership to assess how the site funding mechanism has impacted community involvement at the network, CTU and CRS level.</p> <p>Identify expectations for CAB support and funding that tie into cross-network community evaluation and make actionable recommendations to network leaders and DAIDS.</p>	Adequate site-level CAB support.	Ongoing.	Held three conference calls and refined the draft survey to determine how informed CAB members and site staff are of support available to CABS and allocation of resources. The working group held a joint conference call with the Evaluation Working Group and decided to combine the Evaluation and Site-Level Funding survey questions. The groups will solicit input from HANC, the network liaisons and CSI to assist in survey refinement and administration.
Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming network recompetition and restructuring process.				
Community Partners	<p>Solicit input from networks and other interested groups to provide input and recommendations to DAIDS regarding the Network recompetition and restructuring process.</p>	Identify network and community concerns and provide input in shaping the DAIDS recompetition and restructuring process.	Ongoing.	Elected a new NLOG/SWG member and new CP members. Held discussions with CP Chairs, CP Executive Committee and CP regarding the role of CP in soliciting input.
Objective #6: Utilize CP to provide input and recommendations to ensure that the HANC cross-network Legacy Project achieves increased inclusion of African-American and Latinos/Latinas in HIV prevention and therapeutics research.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Community Partners	Work closely with the HANC cross-network Legacy Project to identify and address common issues relating to community involvement.	CP reps will serve on the HANC Legacy Project Work Group and collaborate in consultation with the CP Executive Committee and related working groups.	Ongoing throughout Year.	Held discussions with CP Chairs, CP Executive Committee and CP regarding the role of CP in soliciting input. Three CP members agreed to serve on the HANC Legacy Project Working Group.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Develop a cross-network contact list				
Communications Working Group	Create a cross-network contact list for staff reference.	Identify network counterparts and facilitate communication amongst network staff.	Completed initial contact list.	Posted cross-network contact list on HANC portal. Updates will be provided on a quarterly basis.
Objective #2: Develop a network newsletter library				
Communications Working Group	Create a network newsletter library on HANC portal and public sites.	Share network news and activities	Completed.	Objective achieved. HANC staff developed a reference library on the HANC portal and duplicate library on the public site. The code is designed to filter out HANC-member only newsletters when publishing to the public site.
Objective #3: Share communications tools and experiences				
Communications Working Group	Establish monthly conference call schedule and determine topics of interest.	Share industry best practices, resources, recruitment tools, and study results dissemination experiences.	Completed.	Shared network websites and portals, discussed network use of Facebook, and reviewed results dissemination communications plans. The group discussed HPTN 035 and RV 144 media plans and coverage at length. HANC staff conducted one-on-one interviews with all Working Group members and will incorporate feedback into future call discussions.

Training Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Identify and provide access to cross-network standardized training for high priority topic areas.				
Training Committee	Identify and discuss training needs and ways to provide access to trainings. Use HANC portal team site for information sharing, training announcements, training requests, and document development.	To address training needs.	Ongoing.	PPD finalized a draft template based on previous training needs assessments created by the networks. Template to be discussed and reviewed in January by the Committee. The existing source documents/essential documents training has been retooled and a session was given during the DRTE in September. Based on the feedback received, additional changes may be made to the training. DAIDS is considering the release of this training via a series of webinars or a blended learning approach (self directed learning, webinars, DRTE's etc). The Committee continued their discussions around challenges with informed consent. Addressing issues with consenting illiterate and decisionally impaired participants was discussed in detail. In order to obtain more information around how sites currently consent these populations, the networks representatives will query their sites to see who has processes and techniques in place that they can share with the Committee in Q3. In regards to a new site start-up guide, the networks found that they supplied new site staff with adequate information. To address the issue of making more detailed information available with DAIDS ES applications, the web pages were added to the HANC public website. (see HANC public website section for details). The CAB Training materials were presented to the Committee. See Community Training section for details and next steps.
Objective #2: Continue the development of core training materials addressing risk reduction counseling in biomedical prevention and treatment trials.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Risk Reduction Counseling Training Working Group	Meet on regular calls to develop and review the training curriculum and ensure the project stays on track and within budget.	Improve the quality of risk reduction counseling in biomedical prevention and treatment trials.	August 2007-TBD.	<p>The pilot training for the 6 South African sites was launched. Go-sessions with the 6 Latin American pilot sites were held to preview the various components of the pilot before launch. All contact information for each site was compiled. Monthly training of mentor calls have continued with the 6 pilot mentors. On-going biweekly check-in calls with SMI and the HRCT development team continue as planned. Monthly HRCT Executive Committee calls continue as planned.</p> <p>Supplemental funds were received from the NIMH to expand this curriculum to include two additional modules on adherence and couples counseling. Subject Matter experts were identified to work on the development of these modules. Planning to hold a F2F for the HRCT expansion in Q3 is underway.</p>
Objective #3: Develop a modular administrative and fiscal training program that supplements NIAID's Grants Policy and Management Training.				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Admin-Fiscal Training working group	Reconvene the working group to review grants management on-line trainings recently made available by the OIEA and identify gaps where additional training is needed.	Avoid duplication of effort and provide a comprehensive grants management training curricula to all CTU/CRS.	Completed in Q2.	Feedback was received from all Admin-Fiscal WG members. All thought the online grant management tutorial materials were well done and comprehensive. There was one outstanding area in which a need was not met and that was personnel. Some networks suggested more information on different roles and responsibilities or further resources on travel. Each network varied in unmet needs. Jane Reynolds had spoken to the DEA about the unmet needs in the personnel category that the networks requested additional information for. The DEA is going to go back and look at their live workshop materials to see if there were exercises they could include in their online tutorial. Out of all of the objectives, majority were met. The consensus was not to reconvene the WG.
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

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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.				
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.	Ongoing throughout year	HANC has had monthly calls with OCSO leadership to facilitate communication with networks and sites about funding deadlines for year 4 and OSCO Director Manizhe Payton joined one of the Network Leaders Group call to discuss these issues. HANC posted OCSO SOPs on the HANC web site.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #2: 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.				
Network staff, OPCRO and OCSO	Develop a cross-network SOP addressing Financial Disclosure reporting requirements.	Harmonize the collection of financial disclosure data across the networks for their benefit and that of site investigators.	Ongoing.	HANC has had monthly calls with network and DAIDS reps to prepare a draft SOP for network review committee and DAIDS consideration. Draft SOP was submitted to constituents in August and the WG is awaiting feedback.
Objective #3: Work closely with network staff, OPCRO, OCSO and other DAIDS offices to identify and address priority site management issues.				
Network Leaders, OCSO, OPCRO	Identify an evolving list of site management issues and opportunities. Work closely with network staff, OPCRO, OCSO and other DAIDS offices to address priority site management issues.	Improve communication and site operations.	Ongoing.	HANC conducted every other month calls with OPCRO and OCSO and monthly calls with OCSO to address site management issues.
Objective #4: Investigate the feasibility of the establishment of a centralized IRB review process for network protocols.				
Network Leaders	Review the experience of the HVTN in establishing a central IRB for HVTN 505.	Address potential utility, costs and benefits of centralized IRBs.	Q1.	Renée Holt, RN, JD, MPH, Regulatory Affairs Manager of the HIV Vaccine Trials Network. Discussed the HVTN's experience establishing a centralized IRB at the FHCRC on the July 2009 NLOG call. Based on that experience the other networks did not express enthusiasm for establishing central IRBs at this time.
Objective #5: Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks.				
Cross-Network Site Coordinator working group	Provide a discussion forum dedicated to addressing significant issues common across the networks that need to be addressed.	To address issues of common concern and harmonize policies and procedures regarding site-level operations.	Ongoing.	Developed a Cross-Network Site Coordinator working group proposal and shared with DAIDS, Network Leader's, Network Core/ Ops Centers which was approved. Identified WG membership across the networks. Working Group will begin meeting in Q3.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
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.				
DMC Harmonization Working Group	Implement Information Technology Best Practice Standards developed in Year 2 at DAIDS Clinical Trials study sites and affiliated laboratories. Monitor infrastructure changes.	Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems.	Review and updating ongoing	Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. IT Best Practices are informing IT training in development by DAIDS staff.
Objective #2: Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization.				
DMC Harmonization Working Group	Maintain code mappings across LIMS systems and modify specimen inventory data elements as requested by SCHARP to track and QA data. Work with individual collaborating partners to ensure that previously identified common data elements are included and supported in electronic manifest files readable across multiple systems and reported back to SCHARP in an inventory data feed.	Electronic manifest files readable across multiple systems and reported back to SCHARP as part of an inventory data feed.	Ongoing.	Discussions with DAIDS are ongoing.
Objective #3: Identify issues and determine how data collection for transgender participants in DAIDS-funded HIV/AIDS clinical trials should be best conducted.				

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DMC Harmonization Working Group	Work with the HVTN Transgender working group to identify issues around transgender participation in clinical trials and further develop improved data collection questions.	Improve data collections tools to better capture data on transgender participants while respecting their unique concerns.	Ongoing.	Working group was not convened this quarter. Activities will resume in Q3.
Objective #4: Identify site DMC training and support needs and in collaboration with the cross-network lab and training groups develop recommended funding and implementation suggestions to address them.				
DMC Harmonization Working Group, Training Committee	Collaborate with the cross-network Training Committee to identify and address data management training needs.	Inform training plans and ensure that sites receive the data management training necessary to participate in clinical trials.	Ongoing.	Standing opportunity for DAIDS staff to address DMC training-related concerns. Ongoing discussion of DAIDS Learning Management System (DAIDS LMS) training at DRTEs.
Objective #5: Harmonize MedDRA coding for AIDS Defining Events				
AIDS Defining Events Working Group	Reconcile CDC and WHO diagnostic classifications with MedDRA codes	Realize DAIDS' mandate to use MedDRA codes in DAIDS-funded clinical trials	Ongoing. Expect resolution in Q3.	Mappings have been completed and up-versioned to the current MedDRA standard. SDAC coders are running beta tests with mappings and HANC staff sent a request for review assistance from select DAIDS-affiliated clinicians and WG is preparing to submit mappings for clinical review.
Objective #6: Implement ClinicalTrials.gov results reporting requirements.				
DMC Harmonization Working Group	Implement new reporting requirements. Clarify responsibilities of DMCs and networks.	Minimize impact of changes in reporting through preparation and sharing concerns with DAIDS leadership.	Ongoing.	HANC staff disseminated draft policies to DMC WG and provided opportunity for DMCs to discuss issues on monthly calls.
Objective #7: Develop a "DAIDS Contacts FAQ" for data management-related issues.				
DMC Harmonization Working Group	Develop a contact list for DMC-related areas within DAIDS	Allow DMC staff to contact the appropriate DAIDS contact, to facilitate conversation, and expedite resolution of questions.	Completed.	DMCWG, OPCRO, and OCSO contributed to a Contacts FAQ. The FAQ is posted on the portal and was announced in the HANC newsletter.
Objective #8: Harmonize Clinical Event Collection policies and procedures to make recommendations on Adverse Events Reporting.				

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DMC Harmonization Working Group	Coordinate and harmonize ongoing activities at DAIDS and the networks around clinical event data collection and adverse event reporting.	Create consistent policies and procedures for clinical event data collection and adverse event reporting.	Ongoing.	This objective is addressed in ongoing calls with OPCRO and the DMC Harmonization Working Group. HANC assisted with collating comments on the DAIDS revised Manual for EAE reporting.
Objective #9: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS).				
DMC Harmonization Working Group	Provide DMC perspective and feedback to DAERS program staff and DAIDS leadership.	Ensure DMC systems are considered in the development and implementation of policies relating to DAERS.	Ongoing.	Opportunity to discuss experiences using DAERS on monthly and ad hoc conference calls.
Objective #10: Facilitate cross-network Appendix Merger Project Working Group				
Cross-network Appendix Merger Project Working Group	Review clinical and coding recommendations from a cross-network perspective.	Reconcile ACTG/IMPAACT diagnostic code appendices 40, 50, and 60 and merge into one appendix; i.e., Appendix 100.	TBD.	Awaiting clinical and coding recommendations based on clinician review. Sent project update to WG members. Added INSIGHT representation to group.
Objective #11: Develop a Serious Adverse Events/Expedited Adverse Events Reconciliation Policy				
DMC Harmonization Working Group, OPCRO, RCC	Develop a cross-DMC SAE/EAE Reconciliation policy.	Standardize SAE/EAE Reconciliation reporting procedures.	Ongoing.	Developed draft policy in consultation with representatives from RCC and Safety and Pharmacovigilance Team. Policy is under review by OPCRO. Next steps pending OPCRO feedback.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Work with CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes.				
Evaluation Measurement Task Force	Hold monthly calls with each working group and CSI to advance the development of an evaluation system.	Develop evaluation metrics and processes to evaluate DAIDS and network success and identify opportunities for improvement.	Ongoing.	Calls with the EMTF planning group are ongoing every other week. Results of preliminary evaluation efforts of the EMTF were presented to the Network Leadership Group in November.

HANC Cross-Network Legacy Project Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q2
Objective #1: Develop supplement proposal for a HANC cross-network Legacy Project.				
Legacy Project Leadership Team	Draft a proposal for supplemental funding for a HANC cross-network Legacy Project detailing the project scope, intent, timeline and criteria to determine project success.	Enhanced cultural competency within the networks and build relationships of trust with African-American and Latino communities within the U.S. to enhance participation of African-Americans, Latinos, and Latinas in network trials.	Completed proposal and submitted in Q1.	Proposal submitted in August and supplemental award notice was received in September.
Objective #2: Develop an effective and efficient transition strategy from HVTN Legacy Project activities to HANC cross-network Legacy Project activities with clear definitions of synergy and cohesion while still maintaining a clear distinction between the two projects.				
Legacy Project Leadership Team	Develop a transition plan to allow the HVTN Legacy Project and the HANC cross-network Legacy Project to work collaboratively and seamlessly with each other and collaborators.	Develop both a collaboration and distinction between the HVTN Legacy Project and the HANC cross-network Legacy Project.	Began meetings in Q1, ongoing in Q2.	Regular meetings were held with HVTN Legacy Project and HANC to discuss the new HANC cross-network Legacy Project and its relationship with the HVTN Legacy Project.