

September 2017



## UPCOMING MEETINGS

Sep 7-10: 2017 USCA;  
Washington, DC

Oct 18-20: HPTN Re-  
gional Meeting; Jo-  
hannesburg, South  
Africa

Oct 23-25: 2017  
HVTN Conference;  
Seattle, WA

Oct 25-26: 11th Na-  
tional SBSRN CFAR  
Meeting; San Francis-  
co, CA

Mar 4-7: CROI 2018;  
Boston, MA

Mar 18—21: 2018  
MTN Annual Meeting;  
Bethesda, MD

Jun 20-24: 2018 An-  
nual ACTG Network  
Meeting; Washing-  
ton, DC

Oct 22-25: HIVR4P  
2018; Madrid, Spain

Jul 14-17 2019: STI &  
HIV World Congress;  
Vancouver, Canada

For details on these  
and other events, go  
to the [HANC calen-  
dar](#).

FOLLOW US ON 



[www.hanc.info](http://www.hanc.info)

1100 Eastlake Ave E.  
Seattle WA USA 98109

## HANC & Network Announcements

**HANC:** Network Working Group: Following the postpone-ment of PF Pilot 1 (more information about the postponement here), NIAID established three working groups to assist in de-veloping strategies, processes, and procedures that streamline and standardize core business processes related to distribution and payment of protocol expenses within the HIV/AIDS Clinical Trials Networks. The three workings groups include: 1) Net-work and NIH staff; 2) CTU/CRS leaders and NIH staff; and 3) NIH staff only. HANC is facilitating the first of these working groups, which held its first call on August 23. HANC is currently meeting with representatives from each network to discuss contracting, invoicing, and reimbursement processes for PF in order to identify opportunities for harmonization.

HANC will host a webinar titled, "Improving the HIV Youth Prevention and Care Continuums: The Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) on September 18 at 10am PT/1pm ET. Dr. Sonia Lee, a Program Officer at NICHD, will present on the webinar. The webinar will provide an informative overview of the ATN and their research priori-ties. For more information and to register, [click here](#).

ACTG recently released its latest [newsletter](#). In this edition, you'll read about:

- ACTG Protocol A5345
- National HIV/AIDS Aging Awareness Day
- A major milestone hit by the REPRIEVE Trial
- The ACTG will support up to two researchers from its international sites to receive internships to attend the SDACT at the Center for Biostatistics in AIDS Research, Harvard TH Chan School of Public Health (HSPH). Applica-tions are now open.



The HIV Prevention Trials Network (HPTN) and WITS RHI co-sponsored a stakeholder meeting for the HPTN 084 study (evaluating long-acting cabotegravir for pre-exposure prophylaxis) in Cape Town, South Africa on August 10-11, 2017. This meeting, part of an ongoing stakeholder engage-ment strategy, brought together approximately 150 attendees from eight countries comprised of representatives from gov-ernmental and nongovernmental organizations, civil society groups, research staff, and community members who are com-mitted to identifying HIV prevention strategies that address the diverse needs of their communities. The countries carrying out HPTN 084 that were represented at this meeting include Bot-swana, Kenya, Malawi, South Africa, Swaziland, Uganda, and Zimbabwe. The anticipated outcome of this meeting was an understanding of the HPTN 084 study through dialogue, mutu-al understanding, and partnership with key stakeholders. HPTN

084 will be implemented throughout sub-Saharan Africa in 20 selected clinical research sites.



**HIV VACCINE  
TRIALS NETWORK**

The HVTN continues to enroll three large HIV efficacy trials. HVTN 702 is enrolling 5,400 women in South Africa. HVTN 703 is enrolling 1,500 women in sub Saharan Africa, and HVTN 704 is enrolling 2,700 men who have sex with men and transgender volunteers in the United States, Switzerland, Peru, and Brazil with both being conducted in partnership with the HPTN.



In mid-August, IMPAACT P1108, a Phase I/II, multi-center, exposure-controlled, dose-finding age de-escalation study of Bedaquiline (BDQ) in HIV-infected and HIV-uninfected pediatric popula-tions with multidrug-resistant tuberculosis (MDR-TB) disease, opened to accrual. The study will evaluate the pharmacoki-netics, safety and tolerability of BDQ in combination with an optimized individualized MDR-TB therapy over 24 weeks in infants, children and adolescents (0 to <18 years of age) with clinically diagnosed or confirmed intra-thoracic MDR-TB who have received 2-12 weeks of routine MDR-TB treatment prior to enrollment. Participants will be enrolled across five sites in South Africa, India, and Haiti. More information is available [here](#) and at [NCT02906007](#).



MTN will be hosting a work-  
shop at the upcoming United  
States Conference on AIDS  
(USCA), Sept. 7-10, Washing-  
ton, D.C. The workshop, Let's

Get Lubricated: Lube safety, access and advocacy, will be held Thursday, Sept. 7 from 10:15-noon, and will address the needs for clear public health messaging around the use and safety of lubes in the U.S. by gay men and other men who have sex with men, and provide an update on the development of lube-based HIV prevention products. Expert panelists will share their insights about the challenges and opportunities involved in providing safe and accessible lubes to all who need them.

A stakeholder consultation for [MTN-034 \(REACH\)](#) – a study of the dapivirine vaginal ring and oral PrEP in adolescent girls and young women at sites in Kenya, South Africa, Uganda and Zim-babwe – was held late August in Kampala, Uganda, with a simi-lar meeting planned for Kenya in October. The meetings are being held in partnership with AVAC and in-country organiza-tions, and will provide an update on study status and timelines and engage with a broad base of stakeholders, including teen girls and young women, about issues that may affect in-country approvals and study implementation. Pending all ap-provals, the REACH study is slated to begin early 2018, and will be enrolling 300 young women ages 16-21.



## REMINDERS

- The “[Portal Trainings & FAQ](#)” pages and documents have been updated for SharePoint 2010.
- Have you ever wondered how to reach a colleague at another network or DAIDS? Check out the [cross-network contact list](#), the [DAIDS staff list](#), or the [DAIDS Topic-specific contact list](#) on the left-hand navigation bar of the [portal homepage](#).
- **Did you know?** NIAID posts funding opportunities to its public website. For more details, [click here](#).
- Check out the [NIH Clinical Regulation website](#), created with the goal of helping researchers learn about international clinical regulations. Users can compare clinical regulations between countries in navigable side-by-side format, in topics such as Ethics Committees, Sponsorship, Clinical Trial Lifecycle, and more!
- Did you know you can access real time accrual information and protocol documents on the HANC portal? [Click here to go to the Quick Protocol Summary!](#)

## HELPFUL TIPS

- Forgot your portal password? Reset it by going to [Log On Help](#).
- Find many HIV/AIDS [resources and links](#) [www.hanc.info](http://www.hanc.info).

FOLLOW US ON 



[www.hanc.info](http://www.hanc.info)

1100 Eastlake Ave E.  
Seattle WA USA 98109

## HANC Program Highlights

**Behavioral Science:** As mentioned in an earlier newsletter, Behavioral Science Consultative Group members Jane Simoni, Barbara Mensch, Mallory Johnson, Rivet Amico, and Sybil Hosek conducted a post-hoc analysis of VOICE-D trial data and created a [poster](#) for presentation at Adherence 2017. The BSCG members are currently working on a paper summarizing their findings. Once the paper has been accepted for publication and is published, the paper will be shared with the BSG listserv.

**Community Coordination:** Community Partners (CP) representatives will be attending the United States Conference on AIDS (USCA) September 7-10 in Washington DC.

CP/HANC will be hosting a webinar focused on the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) and their research priorities in the near future. A link to register for the webinar has been posted under the “HANC” update on the first page.

CP will be holding its annual F2F Meeting October 28-29 in Washington DC and is currently finalizing the agenda and presenters.

**Data Management Center (DMC):** The DMC Working Group discussed further implementation details related to the new DAIDS requirement to collect investigator signatures on CRFs as of October 1, 2017. OCSO released a memo on 7/18 outlining the timeline for this new requirement.

**Evaluation:** The Evaluation Working Group discussed each network’s practices related to interim site performance evaluations. The group also discussed opportunities for harmonizing the metrics related to data management across the networks and the DMCs.

**Financial Disclosure:** The annual solicitation is set to occur on September 21, 2017.

**Laboratory:** VQAAB, LTC, and LFG discussed the recent safety notice recall that Abbott had sent out for certain lots of the Real Time HIV-1 assay. There is an issue with false “Not Detected” results for HIV samples less than 120 Copies/ml when using 0.6 mLs of plasma. After discussion, the networks will send out a guidance memo for their labs. VQA will continue monitoring data for false negatives. ACTG, IM-PAACT, and TBTC will collaborate in drafting an implementation plan for the TB Mycobacteriology Source-Book Guidelines once finalized. TBLD-WG is overlooking the plan. Furthermore, a TB working group have been organized to oversee the development of the

Training Module supporting the Cross Network TB Infection Control SOP. Power Train will be the subcontractor to develop the web-based modules. The WG is gathering requirements to define the goals. TB-EQA contractor, MRI-Global, updated TBLD-WG in their recent activities including but not limited to site visits, building isolate repository, and researching new technologies for diagnostics. Cold Chain Guidelines Working Group has re-convened to finalize the Guidelines document.

**Legacy Project:** The latest edition of the Be the Generation eNewsletter is available, featuring updates from the HPTN, HVTN, MTN, and HANC. Check it out in [English](#) and [Español](#).

The Legacy Project has partnered with the USCA Faith Coalition to arrange a Faith Pre-Conference to the United States Conference on AIDS (USCA) on September 6. People of faith, faith leaders, and people working in the HIV/AIDS response are invited to gather for a one-day, multi-faith conference. The Legacy Project has organized a panel on the intersection of faith, HIV, and stigma that will take place as part of this day-long pre-conference. Please plan your USCA travel accordingly and [register](#) for the USCA 2017 Faith Pre-Conference today!

The Women’s HIV Research Collaborative is hosting a workshop at the United States Conference on AIDS: “The Secret Garden: Unlocking the Mysteries of the Vaginal Microbiome,” Friday, September 8 from 9 to 11 a.m. This workshop features four of the nation’s foremost experts on women’s health and HIV: Gina Brown (Office of AIDS Research, NIH), Dazon Dixon Diallo (SisterLove, Inc.), Katy Godfrey (Division of AIDS, NIH), and Sharon Hillier (Microbicide Trials Network).

The Women’s HIV Research Collaborative is leading a national campaign to encourage people to submit comments focused on the domestic HIV research agenda for women to the NIAID HIV/AIDS Network Refinement process. Later in September, the WHRC will begin disseminating guidelines for people to submit women-centered recommendations to the Network refinement process.

**Network Leadership:** The Network Leadership Group discussed the draft reportable protocol deviation proposal circulated by OCSO on their August 16, 2017 monthly call. Comments will be submitted by September 1 to OCSO by the Networks in collaboration with their SDMCs.

**Research Site Management & Clinical Trials Logistics:** The Site Coordinators Working Group discussed the recent webinars hosted by OCSO related to the CTU recompetition. A recording of those webinars is publicly available [here](#).