

October 2017



## UPCOMING MEETINGS

Oct 18-20: HPTN Regional Meeting; Johannesburg, South Africa

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

Oct 25-26: 11th National SBSRN CFAR Meeting; San Francisco, CA

Feb 21-22: HVTN 2018 Regional Meeting; Cape Town, South Africa

Mar 4-7: CROI 2018; Boston, MA

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

June 8-10: Adherence 2018; Miami, FL

Jun 20-24: 2018 Annual ACTG Network Meeting; Washington, DC

Oct 22-25: HIVR4P 2018; Madrid, Spain

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

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1100 Eastlake Ave E.  
Seattle WA USA 98109

## HANC & Network Announcements

**HANC:** The HANC-facilitated working groups have started revising their annual work plans. The 2018 Work Plan will be reviewed by the Network Leadership Group on their call in November.



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

- The future of the ACTG Network.
- An update to ACTG Clinical Trial A5360.
- How hurricanes impacted ACTG Network Clinical Research Sites.
- Find out when the next ACTG Network Meetings are.



The HPTN will hold a regional meeting for African sites October 18-20, 2017 in Johannesburg, South Africa. The

intended audience includes African CTU/CRS staff participating in HPTN 071, 075, 076, 077, 081, 082, and 084; Principal Investigators/IORs; and CRS key study staff (study coordinators, study clinicians/nurses, laboratory representatives, pharmacists, and community staff responsible for community engagement and cohort recruitment & retention). Other attendees will include HPTN leadership, invited speakers, sponsors/NIH, and potential new partners, investigators, & sites.

The goals of the regional meeting are to:

- Enhance and support new ideas generation by African investigators
- Enhance partnership and foster engagement between HPTN leadership and site leadership and staff
- Enhance the quality of study conduct through sharing successful experiences from sites implementing key HPTN trials in sub-Saharan Africa

Read more about the 2017 Regional Meeting [here](#).



**HIV VACCINE**  
TRIALS NETWORK

The HVTN continues to enroll three large efficacy trials. HVTN 702 is a vaccine trial building on the results of the Thai

Trial (RV144), involving 5400 men and women at 15 clinical trial sites in South Africa. Over 1600 volunteers have been enrolled. The two AMP Studies, a partnership between the HVTN and HPTN, are testing a broadly neutralizing antibody to see if it is safe and effective for preventing HIV. HVTN 703/HPTN 081 will involve 1500 women at 20 clinical trial sites in sub-Saharan Africa, and has already enrolled over 1100 women. HVTN 704/HPTN 085 will involve 2700 men and transgender individuals who have sex with men, and is ongoing at 24 clinical trial sites in Brazil, Peru, Switzerland, and the US. Over 1700 people have been enrolled. The HVTN is also preparing to launch a fourth efficacy trial in the fourth quarter of 2017. The total enrollment across these 4 efficacy trials will be 12,200 volunteers!

The HVTN will be holding a Regional Meeting February 21-22, 2018 at the West Cape Town, Cape Town, South Africa.



IMPAACT is pleased to announce that the P1078, TB APPRISE, has successfully closed to follow-up.

P1078 is a Phase IV, randomized, double-blind, placebo-controlled study of HIV-infected pregnant women and their infants, designed to compare the overall safety and toxicity of isoniazid as tuberculosis prophylaxis given immediately (during antepartum) or deferred until postpartum. The study began in 2014 and included almost 1000 mother-infant pairs across thirteen research sites in Africa, Asia, and the Americas. More information is available on the [IMPAACT website](#).



The MTN held its Regional Meeting from September 19-21 in Cape Town, South Africa. Presentations and plenaries at the meeting focused on the involvement and engagement of adolescents in HIV prevention; the regulatory pathway for the dapivirine vaginal ring; contraceptive counseling in the HOPE vaginal ring trial; and the path ahead for the development and testing of rectal microbicides, among others. Presentations from the meeting can be accessed on the [MTN website](#) by meeting day, with photos from the meeting viewable on [MTN's Facebook page](#).



## 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).

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## HANC Program Highlights

**Behavioral Science:** The Behavioral Science Working Group is currently completing a survey to determine the 2018 Work Plan for the working group. Members of the working group have been asked to complete the survey by October 12 so that the results can be discussed on the BSWG call on October 19.

The Behavioral Science Consultative Group will also be discussing its work plan for 2018 on its next call on October 18.

**Communications:** The Communications Working Group discussed each network’s practices for disseminating study results (particularly those publications that are released years after a study has closed) to study participants as well as the larger community.

**Community Coordination:** Community Partners (CP) will be holding its annual F2F Meeting October 28-29 in Washington DC.

Community Partners representatives provided comments and recommendations to DAIDS leadership for the upcoming Leadership RFA.

**CTU/CRS Working Group:** The CTU/CRS Working Group met for the first time to discuss the group’s charge as well as how this group’s work overlaps with that of the Network Working Group. The CTU/CRS Working Group will be examining and developing recommendations for CTU and CRS-level best practices for addressing the networks’ varied invoicing and reimbursement processes.

**Data Management Center (DMC):** The DMC Working Group discussed harmonization of evaluation metrics related to data management and Medidata Rave. The group also discussed the recent draft version of the network-wide protocol deviation reporting CRF.

**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 began on September 21. Unfortunately, there was a coding error that caused many investigators to receive multiple copies of the solicitation. Once HANC was aware of the error, the timestamp code was fixed and the system returned to normal. HANC apologizes for the inconvenience this error caused. Investigators have until October 21 to complete their disclosure.

**Laboratory:** VQAAB discussed 5 reports during their monthly Call and 2 reports via e-mail: RNA 33 samples 11-15 2nd and 3rd report, RNA 33 5th report, Aptima RNA33, DNA214, DNA DBS214, and Genotype 33. VQA will continually track performance of the Abbott Real

Time RNA assay’s sensitivity and determine when the problem is resolved. LTC discussed developing additional shipping documentation for non-LDMS shipments to assure that integrity of specimen shipment and receipt. ACTG and IMPAACT will be harmonizing their implementation plans for the TB Sourcebook Guidelines that will be finalized soon. TBLD\_WG discussed the latest results from the GeneXpert 2nd panel round and the LPA 2nd panel round including results from the 2nd line drug panels. TBQA will be discussing development of validation panels with Qiagen and SMILE for the Quanti Gold Plus. Cross Network Lab Coordination Working Groups are discussing and honing their work plans for the upcoming year.

**Legacy Project:** The Women’s HIV Research Collaborative (WHRC) has initiated a call to action for participation in the NIAID HIV/AIDS Network refinement process. WHRC members have developed seven women-centered research priorities for NIAID to consider for the 2020-2027 time period. To see this list of priorities and participate in the WHRC’s call to action, contact [bminalga@fredhutch.org](mailto:bminalga@fredhutch.org).

With support from the Legacy Project, the DAIDS Cross-Network Transgender Working Group will pilot its training module, “Introduction to Transgender Communities,” at the HVTN Annual Meeting on Wednesday, October 25 from 1 to 3:30 p.m. in the Princessa I meeting room at the Grand Hyatt Hotel in Seattle. This is the first module in a training curriculum for people in HIV research who may work with transgender participants.

The English version of the new Be the Generation website has been finalized with input from the HPTN, HVTN, and MTN. The website is currently being translated into Spanish and will be publicly available in both languages soon.

**Network Working Group:** The NWG met to discuss each network’s invoicing and reimbursement processes as well as to identify potential areas for harmonization. The group will submit its recommendations to DAIDS by January 2018.

**Pilot 2 Working Group:** The Pilot 2 Working Group received a demo of the IntelliTRIAL clinical trial management system. On the next call, the group will be discussing how a tool like IntelliTRIAL could be used by the networks to standardize procedures related to protocol costing as well as provide deeper insight into site level expenses and their variation across geographic areas and protocols.

**Research Site Management & Clinical Trials Logistics:** The Site Coordinators Working Group discussed recent issues related to site monitoring as well as implementation of new DAIDS requirements related to informed consent, investigator signatures, etc. The group also discussed site-level processes related to invoicing and reimbursement of protocol-related expenses.