

September 2018



## UPCOMING MEETINGS

Sep 6-9: 2018 United States Conference on AIDS; Orlando, FL

Oct 3-7: ID Week; San Francisco, CA

Oct 22-25: HIVR4P 2018; Madrid, Spain

Oct 24-27: The Union World Conference on Lung Health; The Hague, The Netherlands

Dec 3-4: Biomedical HIV Prevention Summit, Los Angeles, CA

Mar 04-07: 2019 CROI; Seattle, WA

Mar 18-21: 2019 National HIV Prevention Conference, Atlanta, GA

May 29-31: 2019 HVTN Full Group Meeting; Washington, DC

Jun 1-5: 2019 HPTN Annual Meeting; Washington, DC

Jun 11-14: 2019 IMPAACT Annual Meeting, Washington, DC

Jun 16-20: 2019 Annual ACTG Network Meeting; Arlington, VA

Jul 14-17: 2019 STI and HIV World Congress, Vancouver, BC

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

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## HANC & Network Announcements

**HANC:** There have been several major policy announcements from DAIDS that have been captured in the Daily Dose postings on the HANC Portal. The policy announcements include:

- Electronic Distribution of Investigator's Brochures (IBs)
- Age and Identity Verification and Co-Enrollment Prevention (AICE) Policy \*submit comments by Sept. 14
- Delegation of Duties Log Policy \*submit comments by Sept. 10
- OPCRO Memo: Timing of consent and re-consent with updated IRB/EC/REOapproved informed consent forms

To view the policies above, please [click here](#).



The AIDS Clinical Trials Group (ACTG) highlights the A5263 study [oral abstract](#) presented during the "Non-communicable diseases: Continued challenges" session at the AIDS 2018 meeting in Amsterdam. This

multinational trial was joint sponsored by the ACTG and the AIDS Malignancy Consortium and co-chaired by Drs. Margaret Borok-Williams and Susan Krown. The purpose of this trial was to evaluate the safety and efficacy of an oral etoposide chemotherapeutic regimen for advanced Kaposi's Sarcoma (KS) in resource-limited settings (given that an oral regimen would provide significant logistical advantages) to intravenous (IV) bleomycin and vincristine (a less expensive option) to IV paclitaxel (the standard of care in resource-rich settings), all co-administered with antiretroviral therapy. The oral etoposide and IV bleomycin/vincristine arms were both closed early due to their inferiority compared to the IV paclitaxel arms in terms of week 48 progression free survival (PFS); PFS rates were 19%, 43% and 63%, respectively. This trial establishes definitively the need for IV paclitaxel as the standard of care for advanced AIDS-associated KS in all settings and should urge an enhanced cancer therapeutic infrastructure and accessibility to essential chemotherapeutic agents worldwide.



The Lancet has published key results from [HPTN 074](#), a randomized, controlled trial conducted among people who inject drugs in Ukraine, Indonesia and Vietnam. Results showed that at 52

weeks from enrollment, participants in the intervention arm nearly doubled their antiretroviral therapy usage, viral suppression and medication-assisted treatment usage compared to the standard of care arm. Mortality was also reduced by more than half with the intervention. The study assessed an integrated intervention combining psychosocial counseling and supported referrals for antiretroviral therapy at any CD4 cell count and substance use treatment for people living with HIV who inject drugs compared to the locally available standard of care.

The HPTN was invited by the National Black Gay Men's Advocacy Coalition (NBGMAC) to present at its AIDS Institute during the 2018 United States Conference on AIDS (USCA). Jonathan Lucas, MPH, will deliver a presentation entitled, "Review of Policy and Research Agenda and Current Research for Black Gay/Bi/SGL Men".



**HIV VACCINE**  
TRIALS NETWORK

Michele Andrasik will be speaking at the upcoming United States Conference

on AIDS (USCA), at Plenary III: Trauma Informed Care: The trauma of surviving and aging with HIV on September 8th from 11:30 AM to 1:30 PM, where she will be providing an overview of the impact of historical trauma on populations with increased vulnerability to HIV. Additionally, the WHRC will be presenting a workshop entitled, The Urgency for Intersectionality in HIV Prevention for Women, on September 6th from 2:00-4:00 PM. Speakers and topics include:

- Morenike Giwa-Onaiwu – The importance of Intersectionality
- Michele Andrasik – Stigma and HIV outcomes
- Kimberly Parker – A Focus on Resilience
- Danielle Campbell – Trauma Informed Care

Steven Wakefield and Reverend Sanders will also participate in USCA as organizing committee members for the 2018 Faith Pre-Conference. This will include a morning plenary update on biomedical prevention for clergy and lay leaders with Dr. Ulysses Burley.



In August, enrollment began in a Phase I/II multisite, randomized, controlled trial of monoclonal antibody VRC01 with combination ART

(cART) to promote clearance of HIV-infected cells in infants (IMPAACT 2008). This proof of concept study aims to show whether broadly neutralizing monoclonal antibodies (bNAbs), an emerging class of HIV-1 therapeutics with direct antiviral properties largely mediated through virus neutralization, will hasten clearance of plasma viremia and HIV-1 producing cells and lead to lower reservoir size when administered concurrently with cART. bNAbs may also facilitate viral clearance through antibody dependent cellular cytotoxicity (ADCC), which promotes killing of HIV-infected cells. HIV-infected infants initiating cART within 12 weeks of birth will be enrolled at sites in Brazil, Botswana, Haiti, Malawi, Zimbabwe and the US. More information is available on the IMPAACT website [here](#) and at ClinicalTrials.gov [here](#).



MTN's Regional Meeting will be held September 22-27 at the Westin Cape Town Hotel in Cape Town, South Africa. Topics covered at the meeting will include

new studies on the dapivirine vaginal ring in pregnant and lactating women, and the implementation of the REACH study (MTN-034) – a Phase IIa study that will evaluate how adolescent girls and young women use the monthly dapivirine vaginal ring and Truvada as daily PrEP and their preferences for either or both approaches. The meeting will also address the implementation of MTN-035, a study to assess the acceptability, tolerability and adherence to placebo rectal microbicides in three formulations: a douche, fast-dissolving rectal tablet (insert) and rectal suppository. For those unable to attend, presentation slides from the meeting will be made available on [MTN's website](#).

Experts from the MTN will be presenting at two sessions at the upcoming United States Conference on AIDS on Friday, September 7. They include, You Down With GPP? Engaging young MSM in HIV prevention scheduled for

9-11 a.m., and a WHRC-led session Can We Deliver? HIV research among pregnant and breastfeeding women scheduled for 4:15-6:15 p.m.

September 2018



## 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 responding to a survey to determine the direction and priorities of the working group in 2019.

The Behavioral Science Consultative Group has begun discussing hosting a webinar series. More details will be available once the topics and dates are chosen.

**Community Coordination:** Community Partners and CRAG are pleased to announce that the abstract, “Combating Global TB/HIV through effective and strategic community engagement”, was accepted as a 90-minute workshop to the Union World Conference on Lung Health, taking place in The Hague, The Netherlands, October 24-27. The workshop will be held in Session Room 1 in the conference Community Space from 10:15 to 11:45 p.m. on October 24.

CP and CRAG are working with the ACTG OR&R Working Group on developing community education and recruitment materials for the PHOENIX study.

Community Partners is delighted to share that Portuguese translation of the Recommendations document as well as materials on Understanding the Clinical Research Process and Principles of Clinical Research are now available. [Click here](#) to view Community Partners training materials in Portuguese.

**Data Management Center:** The Data Management Center Working Group continued to discuss implementation of the safety data reconciliation policy pilot and is scheduled to debrief on the pilot in the coming month. The group also discussed upcoming audits of the DMCs and implementation of new studies in Medidata Rave.

**Financial Disclosure Working Group:** The HANC-facilitated annual solicitation is set to occur on September 21, 2018.

**Laboratory:** The Laboratory Focus Group (LFG) held a joint call with the DAIDS Clinical Laboratory Oversight Team (DCLOT) to continue developing a standardized workflow for initiating and resolving critical items on laboratory action plans. In addition to the LFG call, a sub-working group tasked with leading the project held three calls to design and draft the workflow.

The ACTG Executive Committee announced election results for the Laboratory Technologists Committee (LTC) Co-Vice Chair positions. Please welcome Amy James Loftis (Chapel Hill CRS) and Gerald Tegha (Malawi CRS) as the newest Co-Vice Chairs of the LTC, effective December 1, 2018 to November 30, 2020. Solicitation for general committee membership nominations will be distributed by the Committee the week of September 10th, with a deadline of October 1.

The Cross Network Clinical Pharmacology Laboratories Forum hosted a webinar on the topic of FDA laboratory

inspections, presented by Lane Bushman (CAVP Laboratory Manager at UC Denver-Skaggs School of Pharmacy and Pharmaceutical Sciences).

**Legacy Project:** The latest issue of the Be the Generation newsletter is now available, bringing communities the latest information in HIV prevention research from the HPTN, HVTN, and MTN in both [English](#) and [Español](#). Please refer CABs, community groups, and others interested in HIV prevention research to the newsletter and [Be the Generation website](#).

Legacy and the Women’s HIV Research Collaborative will be well-represented at the United States Conference on AIDS in Orlando, FL, September 5-9, where they will host the following sessions:

- Wednesday, September 5 | 8:30 to 5 p.m. [USCA Faith Pre-Conference](#).
- Thursday, September 6 | 2 to 4 p.m. [“The Urgency for Intersectionality in HIV Prevention for Women.”](#)
- Friday, September 7 | 9 to 11 a.m. “You Down With GPP? Engaging young MSM in HIV prevention.”
- Friday, September 7 | 4:15 to 6:15 p.m. [“Can We Deliver? HIV research among pregnant and breastfeeding women.”](#)
- Friday, September 7 | 4:15 to 6:15 p.m. “Engagement of Latino MSM in HIV Clinical Trials.”

The Legacy Project has had a proposal accepted as a 90-minute workshop to the Union World Conference on Lung Health, taking place in The Hague, The Netherlands, October 24-27. The workshop, “In Solidarity: research and advocacy to decriminalize HIV and TB,” will take place in the conference Community Space from 4:15 to 5:45 p.m. on October 24. The proposal was submitted in collaboration between Brian Minalga (Legacy) and Brian Citro from the Northwestern Pritzker School of Law, and the workshop will involve the following speakers: Allan Maleche, Dean Lewis, John Stephens, Karabo Rafube, and Robert Suttle.

**Research Site Management & Clinical Trial Logistics:** The Site Coordinators Working Group discussed feasibility and implementation of two new DAIDS policies open for public comment, the Delegation of Duties Log (DoD) policy and Age and Identity Verification and Co-Enrollment Prevention (AICE) policy. Policies and associated documents are available on the DAIDS Research Rules & Policies site: <https://www.niaid.nih.gov/research/daids-clinical-research-policies-standard-procedures>

**Youth Prevention Research Working Group:** The Youth Prevention Research Working Group is planning a webinar that will be discussing HPTN 078 and ACTG A5359. Dr. Robert Remien will present on behalf of the HPTN 078 team and Dr. Aadia Rana will present on behalf of the A5359 team. Once the webinar is scheduled, an invite to register for the webinar will be sent out to all HANC collaborators.